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Implementing the End-Stage Renal Disease Program of Medicare

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Health Care Financing Grants and Contracts Reports

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Health Care

Financing Grants and Contracts Report

Implementing the End-Stage Renal Disease

Program of Medicare

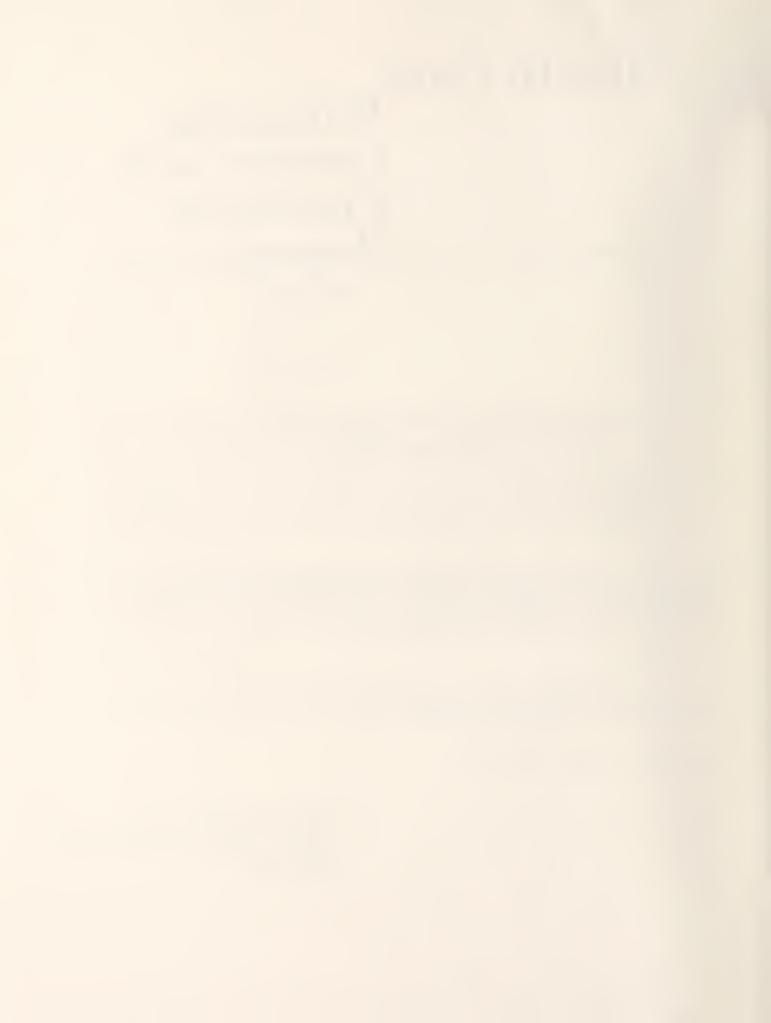
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PREFACE

This is a study of the implementation of the End-Stage Renal Disease (ESRD) program of Medicare, administered by the Health Care Financing Administration of the Department of Health, Education, and Welfare (now the Department of Health and Human Services). Conceptually, implementation includes a planning phase, an operations phase, and an open-ended phase of further design and redesign as learning occurs during operations. This study focuses on three segments of the implementation of the ESRD program:

- o Design of the interim ESRD program;
- o Learning during the interim program; and
- o Design of the long-term ESRD program.

Under the ESRD program, making life-saving treatment available to the relatively few individuals who need it requires large amounts of public resources. It thus encapsulates a familiar dilemma: affirming that life is beyond price may carry with it a high social cost. Such ethical considerations lie close to the surface of all policy discussions of this program, never receding, always reminding us of our technical and clinical prowess, our finite resources, our mortality.

The purposes of this study, however, are not to probe the ethical dimensions of the kidney program, important as these are. Rather, the intention is to analyze the implementation of the ESRD program in order to draw lessons for the program and implications for other possible extensions of national health insurance.

This study reflects several important research activities of The Rand Corporation. Foremost among these is the study of health care financing, including attention to the quality of care of health services. Rand also has a research interest in the implementation of federal government programs in a number of policy areas. These Rand concerns for both substance and process in the delivery of health

services have provided an intellectually rich context for the conduct of this research.

This report is intended for two audiences. The primary audience is those interested in the ESRD program—policymakers in the Congress and the executive branch, physicians, other health professionals, program administrators, health planners, and other interested observers. For this audience, the report provides an account of the first five years of the program. Of course, the complexity of a current billion—dollar program cannot be fully captured in a report of this length; individuals involved in specific events will normally know more about those events than can be reported here. But it is the author's hope that the overall pattern of events and the underlying dynamics of implementation can be more easily understood.

The secondary audience includes those who wish to learn about the processes of implementing federal government programs. The report provides for them a descriptive-analytical approach to questions about the capabilities and limits of federal government action, whether for programs of national health insurance, other entitlement programs, or government activity in general. A growing number of policy analysts, for instance, have observed that government programs often diverge from their initial policy objectives, producing outputs that differ from those originally intended. The cause of this divergence is frequently attributed to "the bureaucracy" or the limited administrative capabilities of the government. In short, something in the "black box" that converts inputs to outputs causes well-intentioned efforts to go awry. The report should illuminate these issues.

These two audiences have differing needs. The former desires a fuller treatment of events than that presented here, the latter a briefer statement. The author has tried to strike a balance between these competing demands, but has deliberately erred in the direction of greater detail. There is an important conceptual reason for doing so, which is both a rationale for and an outcome of the research. To understand what happens in the "black box," it is necessary to examine the gearworks of implementation. To appreciate the

relationship among policy objectives, implementation, and program outputs, one must confront the detailed processes of implementation. And to develop a keener instinct for the capabilities and limits of governmental action, one must have a thorough exposure to how the system works.

The report was prepared for the Office of Demonstrations and Evaluations of the Health Care Financing Administration. The report, of course, reflects the judgments of the author and not necessarily those of the sponsor.



SUMMARY

This report analyzes the implementation of the End-Stage Renal Disease (ESRD) program of Medicare from its authorization in the Social Security Amendments of 1972 through its first five years. Section 299I of that act (Public Law 92-603, October 30, 1972) extends Medicare coverage to individuals under 65 years of age, fully or currently insured, or entitled to monthly insurance benefits under the Social Security Act, and to their spouses and dependent children, if they have permanent kidney failure and require either dialysis or transplantation to live.

The ESRD program began with approximately 11,000 beneficiaries on July 1, 1973, and had an average annual enrollment for 1979 of 56,000 patients. The patient population is projected by the Health Care Financing Administration to grow to 90,000 by 1995, though actual numbers have steadily exceeded previous estimates, and no one is certain where the equilibrium level is. Patients over 65 years of age, eligible for benefits because of enrollment in Medicare, accounted for 5 percent of the average annual enrollment in 1974 (or 1,000 patients) and for 19 percent (or 9,000 patients) in 1978.

The Medicare benefit payments for the ESRD program in calendar 1974 were \$283 million and have increased to an estimated \$1.2 billion in 1979. Benefit payments for the ESRD program now exceed 4 percent of total Medicare expenditures and represent fully 10 percent of

^{*}Although the beginning of the study can be clearly identified, there is no logical end-point to an implementation study. A complex program will always have a substantial amount of unfinished business at any time in its development. Five years, therefore, is admittedly arbitrary and in certain respects an artifact of resource limits on the research project. Furthermore, the end-point is not neat since the components of a program are implemented at different rates. So we have pursued the analysis of particular aspects of the story to a logical stopping point rather than terminating it at a specific date, thus creating some unevenness at the end.

expenditures from the Supplementary Medical Insurance Trust Fund (Part B) of Medicare. In addition to Medicare benefits, fully one-third of the ESRD beneficiaries are eligible for Social Security monthly disability (income support) benefits.

The extremely brief legislative history of Section 299I is examined. This history suggests the difficulty with which legislative bodies confront the conflict between the value that life is priceless and the rudimentary constraint of scarce resources. Two features characterize the statute itself--clarity of central purpose and substantial delegation of authority to the executive branch--and both influence the success and problems of implementation.

In many ways, the ESRD program is a success. Congress established it to pay for the treatment of individuals with kidney failure so that no one lacked access to life-saving treatment for financial reasons. Patients are receiving treatment, bills are being paid, and access to care is no longer an issue. Although program and individual treatment costs are high, the cost control experience includes some encouraging aspects. And there is no reason to believe that quality of care has declined, even though more elderly and sicker patients are now being treated than before.

Success is attributable to several factors. The intent of Congress was relatively clear. Early reimbursement policies, with one notable exception, were sound. Medicare does pay submitted claims. Competence in the system is greatest at the level of service delivery where physicians and nurses run treatment facilities. And patients, who depend upon the program for life-saving treatment, exert a strong demand for an acceptable level of performance.

Notwithstanding its successes, the ESRD program is hardly thought of as a model of implementation. Implementation problems arose from the administrative system, the planning and operational stages, and the substance of reimbursement and medical issues.

The report analyzes the behavior of and relations among the major organizations in the Department of Health, Education, and Welfare involved in implementing the ESRD program—the Office of the Assistant Secretary for Health, the Bureau of Health Insurance of

the Social Security Administration (later the Medicare Bureau of the Health Care Financing Administration), and the Bureau of Quality Assurance of the Health Services Administration (later the Health Standards and Quality Bureau of HCFA). We observed what we believe was a normal amount of bureaucratic conflict, stemming from differing personality characteristics, policy views, jurisdictional interests, and strategic assumptions. Most disturbing is the observed erosion of ESRD policy capability over time.

The process of implementation is described in two stages: planning and operational stages. The initial, time-constrained policy planning period between enactment of a statute and the effective date of a program is critical because it is the period of maximum discretion and because rules adopted at this time govern implementation of health financing programs for many years. We found that operational planning is usually truncated, leaving numerous problems unanswered when operations begin, because planning time is normally absorbed in the resolution of policy planning issues. The start-up phase of operations, consequently, often encounters numerous problems because of inadequate operational planning, a step-function increase in administrative work load, and an understaffed and inexperienced administrative capability. Learning by doing, beyond the start-up phase, is not a rational process of making mid-course adjustments to a predetermined trajectory but rather one of political accommodation to those in the medical community who have benefited from the initial policies. Courts, also, are integral to implementation, adjudicating on contested matters of substance and procedure.

Substantively, the most important reimbursement policy has been the screen, or de facto ceiling, on the per treatment reimbursement of outpatient maintenance dialysis. The screen, which applies to outpatient dialysis whether performed in hospitals or nonhospital facilities, has provided a strong incentive to cost containment. On the other hand, the inadvertently created financial disincentives to home dialysis, which required five years and more legislation to correct, have been one of the least defensible aspects of reimbursement. Both developments are analyzed in the report.

The report also documents the design of ESRD networks--32 regional entities created to coordinate services on a regional basis and to insure that high quality care is provided to patients. Questions about the need for these networks and the likelihood that they will fulfill their objectives are raised by the analysis of the planning stage.

The inability of the government to create adequate data systems for program management is revealed yet another time. One difficulty encountered by the government was that five years were required to securely establish the government's authority to collect cost data from nonhospital, mostly proprietary, limited care dialysis facilities. On the other hand, the establishment of the ESRD Medical Information System was far more within the government's control. But the creation of an adequate system to generate data for rather simple program monitoring has proved to be a long-running, seemingly intractable problem that is only now coming under control.

This report is a highly detailed account of five years of the ESRD program. That is because implementation is an incredibly detailed process. Policy control, moreover, can only be exercised by those able to grasp immense amounts of detail and order it in relation to large policy purposes. It is to that objective of order that this report is directed.

ACKNOWLEDGMENTS

This research required personal interviews with numerous individuals, some of whom are cited in the text. Many others, however, contributed both information and perspective in ways not explicitly indicated. To all these individuals the author extends his gratitude.

Documents in the author's possession constitute an invaluable data source for this report, as will be quickly apparent to the reader. Special thanks go to Milton N. Cikins, Royal Crystal, and Ronald M. Klar for their assistance in building the data base of memoranda and agency reports.

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The greatest debt of thanks is owed to Ellen L. Marks, who helped gather data, prepared background analyses, provided critical commentary on the text, and supplied strong collegial support.

The author bears full responsibility, of course, for any remaining factual errors and for interpretation of the complex events related herein.



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ABBREVIATIONS

Necessarily, the alphabet soup of organizations and activities has been heavily used in this report. The following list of acronyms and their meanings, it is hoped, will help the reader.

ACS	American College of Surgeons
AMA	American Medical Association
APA	Administrative Procedures Act
ASH	Assistant Secretary for Health, HEW
ASIM	American Society of Internal Medicine
BHI	Bureau of Health Insurance, SSA
ВОВ	Bureau of the Budget
BQA	Bureau of Quality Assurance, HSA
CHPS	Comprehensive Health Planning Service
CHU	Community Hemodialysis Unit
CPI	Consumer Price Index
CRD	Chronic Renal Disease Branch, BHI
DMCS	Division of Medical Care Standards, BQA
DSO	Division of State Operations, BHI
ESRD	End-Stage Renal Disease
GAO	General Accounting Office, U.S. Congress
Н	Office of the Assistant Secretary for Health
HCFA	Health Care Financing Administration
HEW	Department of Health, Education, and Welfare
HI	Hospital Insurance
H.R.	House of Representatives
HRA	Health Resources Administration
HSA	Health Services Administration; also Health Systems Agency
HSQB	Health Standards and Quality Bureau, HCFA
I.L.	Intermediary Letter
I.M.	Identical Memorandum
KDCP	Kidney Disease Control Program

KDTC Kidney Disease Treatment Center

KDTDC Kidney Disease Transplant and Dialysis Center

LCF Limited Care Facility

MIS Medical Information System

MRB Medical Review Board

NCC Network Coordinating Council
NIH National Institutes of Health
NKF National Kidney Foundation
NMC National Medical Care, Inc.
NPRM Notice of Proposed Rulemaking

OFAA/HCFA Office of Financial and Actuarial Analysis,

Health Care Financing Administration

OMB Office of Management and Budget

PHS Public Health Service

P.L. Public Law

PRRT Physicians for Renal Replacement Therapy
PSRO Professional Standards Review Organization

RDC Renal Dialysis Center
RFP Request for Proposal

RHA Regional Health Administrators, HEW RMPS Regional Medical Programs Service

RPA Renal Physicians Association
SMI Supplementary Medical Insurance

SMSA Standard Metropolitan Statistical Areas

SSA Social Security Administration
SSI Supplemental Security Income

VA Veterans Administration

VAH Veterans Administration Hospital

I. INTRODUCTION

RATIONALE AND PURPOSE OF THIS STUDY

This is a study of the implementation of the End-Stage Renal Disease (ESRD) program of Medicare, established by Section 299I of Public Law 92-603, the Social Security Amendments of 1972. The period studied is from enactment of the law on October 30, 1972, through mid-1978, a period encompassing the first five years of the program.

Three questions are immediately raised by the subject of this study. Why study the ESRD program? Why study its implementation? And what do we hope to learn?

First, why study the ESRD program? This program claims our attention because life-saving medical treatment is being provided to a very small number of beneficiaries at a very high cost to society, the result of a public policy to affirm the value that life is beyond price even though such affirmation requires substantial public resources. The magnitude of the program is revealed in the following table. Beginning with an estimated 11,000 beneficiaries on July 1, 1973, the inception of the program, the average annual enrollment has grown two and one-half times from 19,000 in 1974 to 47,000 in 1978, and annual benefit payments have increased in current dollars roughly four-fold to an expenditure level of nearly \$1 billion in 1978.

A related reason for studying the program is that its high cost is likely to be borne by society for some time to come. The estimated patient population and annual benefit payments, projected to 1995, are shown in Table 2. The estimates suggest a gradual stabilization of the patient population near the 90,000 level, though the equilibrium point is not known and has been revised upward several times. The projected benefit payments are based upon inflated dollars.

Guido Calabresi and Phillip Bobbitt, Tragic Choices, W. W. Norton & Co., New York, 1978, is an important and provocative essay about the complexities of societal choices where conflict arises between deeply held social values and scarce resources.

Table 1¹
MEDICARE ESRD PATIENT POPULATION AND ANNUAL ESRD BENEFIT PAYMENTS, 1974-1978

Calendar Year Average Annual Enrollment a Enrollment Benefit Payments (\$ millions) 1974 19,000 \$ 283 1975 27,000 450 1976 35,000 598 1977 41,000 757 1978 47,000 947			
1975 27,000 450 1976 35,000 598 1977 41,000 757		Annual	Payments b
1976 35,000 598 1977 41,000 757	1974	19,000	\$ 283
1977 41,000 757	1975	27,000	450
	1976	35,000	598
1978 47,000 947	1977	41,000	757
	1978	47,000	947

SOURCE: Office of Financial and Actuarial Analysis, Division of Medicare Cost Estimates, Health Care Financing Administration, March 1979.

In addition to high present and anticipated costs, the ESRD program deserves attention because it claims an increasing proportion of total Medicare funds. Table 3 compares total Medicare benefit payments with ESRD benefits payments for the Hospital Insurance Trust Fund (Part A) and the Supplementary Medical Insurance Trust Fund (Part B). Although ESRD benefit payments from the Hospital Insurance Trust Fund have risen gradually to 1.3 percent of the total Medicare Part A payments, ESRD benefit payments from the Supplementary Medical Insurance Trust Fund have climbed steeply to nearly 10 percent of total Medicare Part B payments. In other terms, 10 percent of Medicare Part B benefit payments go to 50,000 ESRD beneficiaries and 90 percent to the over 23 million aged enrollees. The ESRD bite is nontrivial!

Further appreciation of the cost of the ESRD program relative to Medicare is gained from the following data: for the year ending

a_{Estimated}.

b Incurred basis; data are calculated according to the date the services were rendered.

¹The figures in this and following tables are estimates provided by the Office of Financial and Actuarial Analysis, Division of Medicare Cost Estimates, Health Care Financing Administration.

Table 2

PROJECTED MEDICARE ESRD PATIENT POPULATION,
AND ANNUAL ESRD BENEFIT PAYMENTS^a

Calendar Year	Average Annual Enrollment	Benefit Payments (\$ millions)
1980	61,000	\$1,350
1985	79,000	2,363
1990	88,000	3,414
1995	90,000	4,551

SOURCE: Office of Financial and Actuarial Analysis, HCFA.

^aThese population projections assume an increase of new entrants of less than 1 percent per year with a slight increase in the numbers of transplants performed. Cost projections assume an inflation factor of about 10 percent per year for hospital costs and about 4 percent per year for non-hospital costs. These assumptions are consistent with the 1979 Annual Reports of the Board of Trustees of the Federal Hospital Insurance Trust Fund and the Federal Supplementary Medical Insurance Trust Fund.

b Incurred basis.

June 20, 1977, per capita incurred benefits for the Supplementary Medical Insurance Trust Fund (Part B) were \$218.37 for 22,605,000 aged enrollees, \$214.39 for 2,233,000 disabled enrollees, and \$13,355 for 31,000 ESRD enrollees.

The second question is why we should study the program's implementation. One important reason is that the ESRD program, in providing nearly universal coverage for kidney failure to the American people, eliminates the private medical market as a basis for setting reimbursement rates. It thus demonstrates the ability or inability of the federal government to create incentives for the efficient utilization of scarce medical resources.

¹¹⁹⁷⁹ Annual Report of the Board of Trustees of the Federal Supplementary Trust Fund, Tables Al and A8, pp. 40 and 47 respectively.

Table 3

TOTAL MEDICARE BENEFIT PAYMENTS COMPARED TO ESRD BENEFIT PAYMENTS FOR PARTS A AND B, 1974-1980 (CASH BASIS)

(\$ millions)

	Ho	Hospital Insurance Trust Fund (Part A)	e A)	Supplem	Supplementary Medical Insurance Trust Fund (Part B)	Insurance r B)
	Medicare	ESRD	ESRD as	Medicare	ESRD	ESRD as
Calendar	Benefit	Benefit	Percent of	Benefit	Benefit	Percent of
Year	Payments	Payments	Medicare	Payments	Payments	Medicare
1974	660,6 \$	69 \$	0.7	\$3,318	\$143	4.3
1975	11,315	115	1.0	4,273	251	5.9
1976	13,340	143	1.1	5,080	373	7.3
1977	15,737	168	1.1	6,038	504	8.3
1978	17,682	210	1.2	7,252	643	8.9
1980 est.	24,267	314	1.3	6,967	936	7.6

April 13, 1979, Table 6, p. 27; 1979 Annual Report of the Board of Trustees of the Federal Supplementary Medical Insurance Trust Fund, April 13, 1979, Table 6, p. 20; and Office of Financial and Actuarial Analysis, HCFA, March 1979. SOURCES: 1979 Annual Report of the Board of Trustees of the Federal Hospital Insurance Trust Fund,

a Cash basis figures are those actually paid out; they are lower than the incurred basis figures because of the lag between incurred obligations and actual expenditures. Furthermore, the program represents a unique instance in which the federal government is simultaneously attempting to

- o Guarantee near-universal access to medical care,
- o Control the costs of delivering that care, and
- o Insure the delivery of high-quality care.

Its experience in pursuing these three objectives simultaneously may foreshadow some of the problems that can be expected if more complex programs of larger scale are undertaken.

Also, since the program provides Medicare coverage to nearly all U.S. citizens having a specific disease requiring particular forms of treatment, it may anticipate extension of Medicare to other specific categorical diseases, for example, hemophilia. And since the ESRD program is a form of catastrophic health insurance—for recurring mainte—nance—therapy rather than for single episodes of expensive treatment, it may illuminate some of the problems that would follow from a general program of catastrophic health insurance.

Our third question is what do we hope to learn from this study. First, we hope to draw lessons that might be useful to the continuing implementation of the program. Beyond this, we also wish to develop the implications for any extension of national health insurance. For this larger objective, the value of this study may depend far less on the comparability of end-stage renal disease to other diseases than on the similarity between ESRD implementation problems and those confronting other health insurance programs. Finally, we hope to learn something about the nature of implementation of federal government policies and programs.

A PROGRAM OUT OF CONTROL?

It is appropriate to ask whether ESRD program costs are out of control, since it is widely perceived that they are. The answer to

¹For a strong critique of this disease-by-disease approach, see National Academy of Sciences--Institute of Medicine, The Report of the Panel on Implications of a Categorical Catastrophic Approach to National Health Insurance, Washington, D.C., June 1973.

this question can be found in Table 4. The current (unadjusted) costs of the program (from Table 1) are deflated to 1972 constant dollars using two indexes--the Consumer Price Index (CPI) for all items and the CPI subindex for medical care. We assume that inflation has affected the ESRD program at least as much as the entire economy but no more than medical care in general; if this is true, these two deflators set lower and upper limits to ESRD program inflation. The \$947 million unadjusted program benefit payments for 1978 lies somewhere between \$572 million and \$623 million in 1972 dollars. Using both deflated cost streams, then, and computing an average benefit payment per beneficiary for the years 1974 through 1978, we find practically no increase for the general CPI deflator and even a slight decrease for the medical items deflator. Admittedly, this is a crude measure which fails to reflect any major changes in the beneficiary population. Even so, this stability in annual beneficiary payments is surprising and suggests a more modest verdict than the costs are out of control.

Moreover, the astronomical cost projects to 1995 (Table 2) are seen in a different light if constant, rather than inflated, dollars are used. If we take the 1978 average benefit payment per patient of \$20,000, the projected program benefit payments for 1980, 1985, 1990, and 1995, respectively, are \$1.22 billion, \$1.58 billion, \$1.76 billion, and \$1.8 billion. These costs are clearly high, but quite different from the inflated projections of Table 2.

The figures above indicate Medicare costs only. But many ESRD beneficiaries also receive Social Security monthly disability benefits (income support) as a result of their medical condition. The true social cost of sustaining the lives of ESRD beneficiaries would also include these monthly disability benefits but data on the interaction of these two programs are nonexistent.

The actual costs of Medicare's ESRD program, though, appear rather stable. Why, then, are they perceived to be out of control? Several factors suggest themselves. One is simply that costs are very high, both for patients and the program, and the awareness of these

COMPARISON OF CURRENT AND CONSTANT DOLLAR ESRD PROGRAM BENEFIT PAYMENTS
AND AVERAGE BENEFIT PAYMENTS PER PATIENT
1974-1978 Table 4

		Annual ESI	Annual ESRD Benefit Payments (\$ million)	nents	Average B	Average Benefit Payments	ts
			Doffeed L.	. CDT Tado	ad.	per ratient	
	Average	ESRD Program,	1972 = 100	1972 = 100		Adjusted by CPI Index	. CPI Index
Year	Enrollment	Onaujusteu Dollars	All Items ^a	Medical ^b	Unadjusted	All Items	Medical
1974	19,000	\$283	\$244	\$254	\$14,895	\$12,842	\$13,368
1975	27,000	450	354	354	16,667	13,111	13,111
1976	35,000	598	447	429	17,086	12,771	12,257
1977	41,000	757	535	495	18,463	13,049	12,073
1978	47,000	947	623	572	20,149	13,255	12,170

almplicit price deflator, Gross National Product, Economic Report of the President, 1979, Table B-4,

bComputed by setting 1967 CPI Medical Care subindex value for 1972 (132.5) equal to 100.

high costs often comes as a rude shock to many people. Furthermore, the figures used in the 1972 Senate debate authorizing the program were unreasonably low and quite misleading and, in early 1973, the subject of a well-publicized controversy. The shift from unrealistic to realistic estimates contributed to a perception of costs out of control. Furthermore, cost projections have generally included an inflation factor, rather than being based on constant dollars. These out-year projections, therefore, tend to exaggerate true costs.

Beyond questions of actual costs, disputed estimates, and inflated projections, other factors contribute to the perception of a program out of control. It is widely appreciated that the proportion of home dialysis patients to total dialysis patients declined sharply with the advent of the program. That the lower cost form of dialysis treatment is not being vigorously promoted, troubles many people. And many are aware that the program confers substantial pecuniary benefits to physicians and facilities, including proprietary dialysis firms. Money is being made off the ESRD program, which makes many quite uneasy. Finally, the implementation of the program, independent of cost considerations, is regarded by many as exhibiting chronic instability, an impression which will undoubtedly be reinforced by this report.

In fact, the ESRD program has been relatively successful in providing access to treatment, its central purpose, and has realized a surprising degree of cost containment, while simultaneously experiencing numerous recurring problems of implementation. Why this is so is revealed in the chapters which follow.

RESEARCH METHODS

In general, we used several different kinds of data, acquired by various means of data collection and interpreted by an iterative process of writing, securing comments on draft materials, and rewriting. We found the respective tasks of data collection, analysis, and presentation to be far more intertwined and far less discrete than anticipated. Comments on draft portions of the report, for instance, often led to the identification of previously overlooked documents and then to face-to-face or telephone conversations that amplified the meaning and context of such documents.

Data sources included individuals and documents. Individuals included Congressional staff, executive branch policy officials, program managers, physicians, and other knowledgeable participants and observers. The "interview" was the basic means for acquiring data from individuals, from formal, semi-structured interviews, to discussions as we rummaged through files, to informal conversations. Some individuals were interviewed more than once, and often a combination of interviews, correspondence, and telephone conversations was used. Documents included both published and unpublished materials. These ranged from reports and internal memoranda to correspondence from both public and private sources. These materials were acquired through direct purchase, provision by individuals, and xeroxing of files.

Several general lessons were learned about the "data," lessons so simple that they bear repeating. The knowledge of any given individual is frequently very detailed about some things and very limited about others, and the perspective of any individual is often quite partial. It was therefore necessary, for any event, to interview several persons. Second, interview data are not reliable without corroboration by documentary materials: memories are not exact and motives are not pure. So the story was built upon data from both sources, with an effort to establish the validity of one source by checking it against another. Third, there is no such thing as a central file; organizations are better at acquiring and keeping their own documents than organizing those generated elsewhere. Also, files are periodically purged, a bonanza to the analyst present at the purging, but an absolute and unknowable information loss otherwise.

In data analysis and interpretation, the main lines of the story were known from official documents, published articles, trade press accounts, and interviews. The fine detail was learned through internal memoranda, unpublished reports, correspondence, and so on—all augmented by informed commentary from participants. An initial draft of portions of the report was circulated to a select number of government officials, former government officials, and involved physicians. Comments helped

Lewis A. Dexter, *Elite and Specialized Interviewing*, Evanston, Illinois, Northwestern University Press, 1970, esp. pp. 3-22.

in the preparation of a final draft report, which was then circulated to approximately 20 individuals. The comments on factual and interpretive material greatly aided the writing of this report, and reliance upon such comments must be considered an integral part of our research methods.

As a general methodological strategy, we concluded that a presentation of the richness of empirical detail was preferred to a more austere analytical presentation. We present the detail within a conceptual framework, to be sure, and we also draw out the lessons we see in the analysis. But we believe that implementation research needs good descriptive accounts, that the empirical detail can point to more general categories of analysis, and that lessons that may have eluded us may be seen by others from the empirical data we have provided.

THE ORGANIZATION OF THE REPORT

In Section II we set forth the conceptual framework for understanding the implementation of the ESRD program. Section III presents an overview of the program. The four successive sections are organized along the lines of the organization of the program itself. Section IV deals with the interim program planning phase, Section V with the interim program learning experience, Section VI with the long-term program planning phase, and Section VII with the ESRD Medical Information System. In Section VIII we present our findings, conclusions, and recommendations.

See Clifford Geertz, *The Interpretation of Cultures*, Basic Books, New York, 1973, pp. 3-30, for a discussion of "thick description" and the rationale for letting meaning arise out of the presentation of empirical detail. See also Abraham Kaplan, *The Conduct of Inquiry*, Harper and Row, New York, 1964.

II. CONCEPTUAL FRAMEWORK

In this section we indicate the relationship of implementation to other stages of the policy process, set forth our conceptual framework for understanding implementation, and relate the ESRD program to that framework. The perspective, it should be emphasized, is on the implementation of federal government programs. No attempt has been made to generalize to the implementation of state and local government programs.

THE POLICY PROCESS

Policymakers and policy analysts generally agree that the policy process consists of a series of discrete stages, though exact terminology often differs. In this report, we recognize the following stages:

Agenda setting refers to efforts by individuals and groups to bring an issue to public attention and then to formal consideration by public officials in order to secure a favorable public policy toward the issue.

Policy formulation is the collective determination of a public policy and includes identifying, debating, and choosing among major policy alternatives. It may express or imply how the chosen policy is to be implemented.

Implementation is the purposeful, organized activity undertaken to transform a policy into a program and the latter into program outputs corresponding to intended objectives.

Termination is the conclusion of activity directed toward implementing particular policy objectives.

Monitoring, review, and evaluation of programs resulting in their incremental modification, major reorientation, or termination are activities considered here to be part of implementation.

Several terms used above require elaboration. *Policy*, in this study, is a purposive collective choice embodied in an authoritative statement of governmental intentions, directed to achieving certain objectives, and containing the obligation to act. Policy may include explicit instructions or implicit assumptions about how implementation

should occur, including who should implement it and how financial resources are to be provided for its implementation. Program refers to the administrative activities undertaken and the resources provided to transform policy objectives into program outputs. Outputs are the actual results that are directly attributable to program activities which, when related to policy objectives, constitute the basis for evaluating programs. Primary outputs are the results that affect the principal target population of the policy, while secondary outputs affect those not in the target population but involved in the production of goods or delivery of services. Outcomes are the broader effects, including indirect and unintended consequences, of the policy and program.

The basic policy for end-stage renal disease is contained in Section 299I of P.L. 92-603 and statements made on the floor of Congress at the time of enactment; subordinate policies are found in the implementing regulations and other official documents. The primary output of the ESRD program is the treatment benefit provided to patients whose kidneys have failed and who require dialysis or transplantation. There are secondary outputs of the program that affect physicians—for example, reimbursement for physician services, other health service professionals, treatment facilities, manufacturers and suppliers of equipment and supplies, and others. Outcomes, or broader effects, might include the increasing proportion of elderly and diabetics in the patient population resulting, in part, from the effective removal of scarcity as a criterion for physician decisionmaking about access to treatment.

Identifying the stages of a process implies a logical, sequential progression from one stage to the next, even though action normally occurs in several stages simultaneously, and though complex patterns of recurring, episodic, and unique interactions tie stages together. The study of implementation, in fact, requires attention to two stages of the policy process—the policy formulation stage and the implementation stage itself—and to the interactions between them. Several reasons justify including both stages in the analysis of implementation. First, the outcome of the policy formulation stage is a policy statement which constitutes a basic input to the implementation stage and a factor affecting the conduct and output of implementation.

Second, the authorizing statute articulating a given policy normally specifies how that policy is to be financed--by annual appropriations, for instance, or by the Hospital Insurance and Supplementary Medical Insurance Trust Funds in the case of Medicare. Third, particular policies enacted in statutory form are usually amendments to a larger body of statute law--the Social Security Act, the Public Health Service Act, the tax code, and so on. Thus, the policy formulation stage often determines who implements a policy because the agency responsible for administering the larger body of statute law will generally be responsible for administering the particular policy. Fourth, the subcommittees and committees of Congress originating the legislation, and primarily responsible for its enactment, remain the active congressional participants in the implementation stage of a policy. Fifth, implementation often leads to the need for policy reformulation, some of which can be accomplished only through new legislation. Finally, on policy grounds, it is essential to include the policy formulation stage within the scope of implementation analysis because recommendations to improve implementation may need to be addressed to the Congress as well as to the executive branch.

IMPLEMENTATION

There are no adequate general descriptive-analytical models of implementation having high practical utility, even though the study of implementation has received renewed research attention in recent years. Fragments of models exist, but the insight they provide is dwarfed by the scope and complexity of implementation problems in the modern state. In this study, therefore, we identify several factors which are important for the analysis of implementation. These are factors pertaining to:

- o Process;
- o Substance;
- o Structure;
- o Motivation;
- o Context.

These factors quite obviously interact with each other, but they also serve as independent analytical focuses. Each is discussed briefly below.

Process Factors: The Stages of Implementation

Implementation can be divided into two basic stages—planning and operations. Planning, which precedes actual program operations, includes both policy planning and operational planning. Policy planning consists of the elaboration and extension of the policy statement. While the latter is normally a statute, and pertinent statements and documents that are part of its legislative history, a frequent expression of policy planning is federal regulations that repeat, clarify, and extend the meaning and intent of the statute. It is policy planning that links the primarily legislative world of policy formulation with the predominately administrative world of implementation.

Operational planning involves the assignment of administrative responsibilities, the development of administrative resources, the establishment of administrative procedures and forms, the preparation of manuals, guidelines, and instructional materials for lower level organizations and personnel, and the conduct of training programs. Some operational planning can occur independently of policy planning, but much is contingent on the resolution of major policy planning issues.

Operations consist of the day-to-day administrative and professional activities that are required in order to deliver services.

Within operations, a useful distinction can be made between start-up operations and ongoing operations. Start-up operations, which are often frenetic, involve getting the actual delivery of services "up and running" and, in the process, completing the unfinished business of operational planning. Ongoing operations represent the institution-alization of routines and procedures developed in operational planning and "debugged" during the start-up phase--routine claims processing, program monitoring and evaluation, and data generation; they are one result of "learning from experience."

Program operations also reveal limitations and deficiencies in policy and thus lead to policy design and redesign activities. Design

may include completion of unfinished business from either policy planning or operational planning and establishment of a line of policy direction by a pattern of consistent, sequential administrative decisions. Redesign may involve modification of initial policy because of its unacceptability to affected parties and modification, or radical change of policy because of court decisions resulting from litigation. Thus, "learning from experience" leads toward both improved operational efficiency and policy reformulation.

At some time, several years after program initiation, an equilibrium may be reached in which all major policy decisions have been adopted and found acceptable and all major administrative processes have been established and understood by those using them. The task of implementation will then have become routinized.

The processes of implementation frequently require adherence to procedure. The issuance of federal regulations is normally governed by the provisions of the Administrative Procedures Act. These provisions require government agencies to publish proposed regulations as a Notice of Proposed Rulemaking in the *Federal Register*; provide for public participation through an adequate period of public comment and perhaps public hearings; analyze the public comment; and, concurrently with publishing the regulations as final rules, indicate agency reasons for accepting or rejecting such comment. Regulations may provide "exceptions procedures" for certain parts; they may also provide for administrative appeal of decisions made pursuant to the regulations. These procedural requirements may constitute an important aspect of implementation.

Substantive Factors: Policy and Implementation Problem Structure

Implementation is affected by the substance with which it deals. The ESRD program is an entitlement program for individuals though not a direct cash-transfer plan, and differs from grant-in-aid programs to state and local governments.

The principal source of the substance or content of implementation is the policy—the authoritative statement of official intentions, in this case, Section 299I of P.L. 92-603. A policy must be viewed

in several ways if its contribution to success of implementation is to be understood. The knowledge of the historical evolution of a policy conveys information about key political actors, underlying value consensus, value trade-offs made in policy formulation, desired objectives, and initial expectations about likely outputs. The likely success of implementation is influenced directly by the clarity of the policy about ends and the relations between ends and means. The complexity of a policy, measured by the number of its major constituent elements and the interactions among the elements, inversely affects the probable success of implementation. The degree of administrative discretion, or the ratio of statutory prescription of administrative action to the delegation of authority to administrators, undoubtedly affects the likely success of implementation, though in an unpredictable, and perhaps unknowable way. And the greater the degree of correspondence between a given policy and the larger, contiguous body of policy in which it is embedded, the more likely implementation will be successful.

A policy usually sets forth several objectives, a set sometimes called the goal structure. The parallel concept of implementation problem structure is useful for describing and explaining the content of implementation. The implementation problem structure is not a simple factoring of goal structure objectives into subobjectives. Rather, it is a transformation of the ends-oriented set of policy objectives into a means-oriented set of the major administrative problems of implementation. The problem structure constitutes the conceptual basis for understanding implementation problems, provides the language for addressing those problems, identifies the necessary standard operating procedures, and establishes the rationale for the administrative division of labor. It also sets the stage for goal displacement to occur. The implementation problem structure is, in short, a template that organizes administrative action, and consequently political conflict, in the implementation stage. 1

Consider this example: A professional golf tournament has a goal structure of providing opportunities to touring professionals to earn money, rewarding the local club with the benefits of being host, letting local enthusiasts see the "pros," and permitting a national television audience to view a major sports event. The implementation

The implementation issue structure is the product of many factors. One is the stablished pattern of agency thought and action. A second is the conceptual legacy bequeathed to the implementation effort by the knowledge, doctrine, and ideological views of the medical community, for instance, about the appropriate way to deliver care. Yet a third source of the issue structure is the organizational patterns and operational tasks of the service delivery setting. Finally, the statute and regulations make both substantive and procedural contributions to the implementation issue structure.

The substance of implementation, then, is determined by the policy, which establishes the goal structure of a program, and by the implementation problem structure, which identifies the major administrative problems requiring attention.

Structural Factors: The Administrative System

Implementation occurs primarily within an administrative context. Previously, the government relied almost exclusively upon bureaus to administer policies and programs. But few bureaus exist in the contemporary federal government that exercise exclusive authority over anything. Instead, the typical administrative system of today is a large, complex, interorganizational network that includes several federal government agencies, federal central and regional offices, state, regional, and local government agencies, numerous decentralized service delivery organizations, as well as nongovernmental organizations from both the profit and nonprofit sectors. Moreover, administrative subsystems exist within these interorganizational networks with responsibility for specific administrative routines, processes, or problems. In the ESRD program, distinct subsystems exist for patient eligibility, facility certification, facility and physician reimbursement, and medical reviews. A given subsystem seldom draws upon the full set of

problem structure of a tournament deals with the following problems: admissions, caddies, clubhouse, concessions, construction, finance, gallery control, golf course conditioning, legal affairs, media promotion and community relations, parking, pro-am, tournament magazine or program, entries, housing and hospitality, scoring and communications, security, transportation, and volunteers.

institutions of the larger network, and different subsystems frequently draw upon different subsets.

Multiple and distinct incentive systems govern the behavior of the numerous organizational entities in the administrative system, and these are not apt to be compatible on all occasions with the objectives of public policy or the program activities of those having primary implementation responsibility. The implementation capability of the administrative system is limited by its interorganizational complexity and the numerous, incompatible incentive systems governing the behavior of component units. Such limitations on capability may be offset by the presence of a dominant organization in the system, one commanding deference from others by reason of political support, legal authority, financial resources, technical competence, and so on.

There are two critical problem areas in the administrative system: authority and financial resources. Authority, in the contemporary federal government, is increasingly concentrated in formal terms and dispersed among numerous entities seeking to define and influence its exercise. As government increases in scope, size, interdependence, and complexity, Congress vests less authority at the bureau level, withdrawing bureau authority in some cases, and more and more in a cabinet-level departmental secretary. Furthermore, in responses to these same forces, Congress tends to be less directive in the legislation it writes and increasingly delegates authority to the administrative discretion of the cabinet secretary. The result, however, is that an overburdened secretary is less and less able to exercise all the authority vested in him, and seeks to compensate for his limitations by increasing the number of personnel and specialized staff units in the office of the secretary. This, in turn, leads to greater competition within the secretary's office among those who would define and influence the exercise of secretarial discretion. There is, moreover, increased tension between the office of the secretary and the operational bureaus of the department. The authority traditionally exercised by bureaus is further eroded. The results are delays in decisionmaking, separation of policy from operations, diffusion of accountability, little obvious

benefit in the exercise of administrative discretion, and no apparent improvement in administrative efficiency. We witness the growth of bureaucracy without hierarchy.

The control over financial resources constitutes the second critical problem. If an agency is dependent for resources on the annual appropriations cycle, it then necessarily shares power with higher bureaucratic authority, the Office of Management and Budget, and the relevant subcommittees of the House and Senate appropriations committees If, on the other hand, its financial resources flow from a financing mechanism like the highway trust fund, or the trust funds of Medicare, then there is far less sharing of power and far more agency autonomy stemming directly from the financing arrangements.

Two other recurring questions affect the administrative system-personnel and reorganization. Personnel problems include frequent leadership changes of both policy and program officials, weak relations between political appointees and higher civil servants, general inability of the government to recruit physicians to federal administrative positions, increasingly uncertain career pathways for program managers, and the often inadequate training and experience of personnel at the base of the administrative pyramid (especially in field offices). Reorganization of government agencies is a constant fact of administrative life, affecting individual careers, altering established and emerging administrative routines, complicating relations among organizational entities, and changing relations with external groups and individuals. Because reorganization seldom bears a clearly discernible relation to improved efficiency, and is often politics in yet another guise, it complicates the prospects for successful implementation.

Within the administrative system, there are a number of bases for cooperation among organizational entities. These include, for example, policy, especially where clarity and consistency is high and complexity is low; hierarchy, particularly where stable superior-subordinate relationships exist and where opportunity for career development can occur; financial dependence, to the extent that control over scarce resources can insure lower level compliance with higher level purposes; information, to the extent that higher levels seek it from

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lower levels for the purpose of policy guidance and control; administrative routines, where consistent patterns can be established for administrative tasks that cross organizational boundaries; incentive system compatibility, if lower level incentives can be established that are consistent with higher level objectives; and a common history or shared values among key individuals in the system.

Numerous bases for conflict also exist among organizational entities. These include, for instance, policy, if it is unclear or ambiguous and thus subject to different interpretations; traditional cleavage among units within the same organization—for instance, department versus bureau, policy versus operations, or center versus field offices; contested jurisdictional boundaries between units in different organizations; contractual relations between public and private organizations; bargaining relations among federal, state, and local organizations; limited financial dependence, to the extent that a significant measure of autonomous behavior exists for some units in the system; the absence of information; the absence of established administrative routines; incompatibility of incentives between lower and higher level organizational units; and the absence of common history or shared values among key individuals in the system.

Motivating Factors: The Behavior of the Relevant Actors

What motivates implementation? It is demands placed on the political system, the incorporation of demands into policy, the provision of resources to enable policy to be implemented, and the purposeful behavior of the relevant actors.

Four broad groups of actors can be identified whose behavior affects implementation: legislative and executive branch officials directly concerned with a particular policy; program managers directly responsible for implementation; parties—at—interest concerned with the direct and indirect outputs of the program; and other high—level officials concerned with related policies and programs. Each group has a different perspective on implementation.

¹See Graham T. Allison, Essence of Decision: Explaining the Cuban Missile Crisis, Little, Brown, and Company, Boston, 1971, for an analysis of the multiple perspectives different actors have toward the same events.

High-level officials directly concerned with a given policy are occupied with a number of policies and programs simultaneously. Their primary concerns for implementation are to pursue their concept of the public interest, balance the implications of one policy for other policies (including future policy options), establish political acceptability, achieve consistency with related policies, and facilitate effective implementation. Program managers participating full-time in implementation are most likely to accept the program as their primary frame of reference, and are concerned mainly with how to make the program work. Their criteria of action include consistency with law and regulation, administrative feasibility, and acceptability to constituency and clientele interests. Parties-at-interest include beneficiaries and service deliverers having intense personal preferences about implementation where their interests are concerned. The fourth group, other high-level officials with related but not direct interests, usually become involved episodically with implementation. Their interests are apt to include the compatibility of the given policy with related policies and with different administrative systems.

Decisionmaking in the implementation stage is widely dispersed rather than highly focused as in the policy formulation stage. In the latter, action typically occurs at a few critical decision points and involves relatively few key legislative and executive officials. But the complexity of both the administrative system and the processes of implementation create numerous decision points and involve many public officials, high and low, as well as numerous private individuals.

In this dispersed decisionmaking context of implementation the relevant actors for any given decision cannot be predicted, only described ex post. Their behavior will be governed by administrative divisions of labor, indirect political involvement representing someone else's interest, jurisdictional conflicts between administrators, and direct self-interest. Efforts will be directed toward establishing or modifying the "rules of the game" and toward seeking favorable outcomes within those rules.

Contextual Factors

The context surrounding a policy affects implementation. This proposition has the force of an apparent truism. Ignoring the proposition, however, carries the danger of insensitivity to important explanatory factors. But there is also a danger of making too much of contextual factors and failing to explain anything.

We identify here three contextual factors believed to affect implementation—historical developments, initial conditions, and concurrent developments. Important historical developments include, at least, the evolution of federal policy and of derived federal programs, the "intellectual history" of a policy relative to the appropriateness of government action, and the accumulation of a technical professional knowledge base about the delivery of the service in question.

The conditions that obtain when implementation begins are to be understood as a snapshot—either the last frame of historical developments or the first frame of concurrent developments. At a minimum, the important initial conditions include the political setting and the power relations among important political actors, prevailing interpretations of the new policy's significance, the "package" of other new policies of which the given policy is one part, expectations about prospects for implementation, the nature and distribution of specific organizational capabilities within the administrative system, and the nature and distribution of capabilities among service providers.

Concurrent developments include the political, administrative, and technical-professional factors that are external to the particular implementation effort: general political developments, the reorganization of federal agencies, turnover among high-level policy officials, the sudden intersection of a given policy with policies previously

¹T. J. Lowi admonishes us to ask about the meaning of a policy "as part of the long line of intention to which a government or an agency of government is committed"; see "What Political Scientists Don't Need To Ask about Policy Analysis," *Policy Studies Journal*, Vol. 2, No. 1, Autumn 1973, p. 66.

Public Law 92-603 was a long, complex statute; many of its provisions were of greater importance than Section 299I, and some provisions had important implications for the implementation of 299I.

regarded as independent, and the changing knowledge base undergirding service delivery. We choose this term primarily to emphasize that implementation can be, and often is, affected by apparently unrelated events occurring in the surrounding context.

The conceptual framework developed above is used in this report in the following way. An overview of the ESRD program is provided in the next section which discusses the substance in terms of the development of policy in Section 299I and identifies the implementation problem structure for both the interim and long-term ESRD programs. Consideration of structure focuses on the constituent organizations of the administrative system and the dynamic relations among them. Major participants are indicated. In Sections IV, V, VI, and VII, then, the emphasis is placed primarily on the processes of implementation.

III. AN OVERVIEW OF THE ESRD PROGRAM

In this section we present an overview of the ESRD program. Successive sections consider the policy, the organization of the program, the administrative system, and the major participants.

THE POLICY

Origins

The ESRD program has its clinical origins in the development in the 1960s of two therapies for chronic kidney failure, hemodialysis and renal transplantation; in the federal policy response to these therapies from 1963 through 1972; and specifically in the Social Security Amendments of 1972.

Healthy kidneys perform several functions. They rid the body of metabolic waste products through the urine. They regulate the volume and composition of body fluids and electrolytes by filtration through the kidneys, excretion of some water and electrolytes, and reabsorption of the rest. An average adult male, for example, filters approximately 180 liters of water through his kidneys each day, discharging perhaps 1.5 liters in urine, and reabsorbing the remaining 99 percent. The kidneys also play a role in the maintenance of blood pressure and in red cell production. Permanent or chronic or end-stage kidney failure occurs when an individual experiences such a degree of irreversible loss of kidney function that, without treatment, death will soon follow. There are several diseases that lead to kidney failure, but end-stage renal disease is their common functional termination state. 2

The term "renal" means pertaining to the kidneys, from ren, the Latin word for kidney.

The most common diseases of the kidneys leading to end-stage disease are glomerulonephritis; interstitial nephritis, including pyelonephritis; hypertension; diabetes; and polycystic disease. Glomerulonephritis is an "inflammation" of the capillary loops in the glomeruli of the kidney. The etiology of glomerulonephritis in many patients has not been identified, while in others the process results from an "allergic" or immune reaction initiated by known factors like infection

In the 1960s, two means of treating end-stage renal disease were developed. Hemodialysis is the process of removing toxic waste products from the blood by means of an artificial kidney. Renal transplantation is a surgical procedure whereby a healthy kidney from some other human is substituted for an individual's nonfunctioning kidney. Although there are two other therapies in use today--peritoneal dialysis and hemofiltration, hemodialysis and renal transplantation are the main concerns of this report.

After the emergence of dialysis and transplantation, a decade of federal policy development took place before the establishment of the Medicare ESRD program. ² In 1963, the Veterans Administration (VA) announced its intention to establish 30 dialysis centers in VA hospitals over a three-year period. Although the original schedule was not strictly followed, by the end of fiscal year 1972 the VA had established 44 dialysis treatment centers. It had also initiated a home dialysis program in fiscal year 1969, and had opened the first home dialysis training units in fiscal 1971. Satellite dialysis, involving dialysis in a nonhospital, nonhome setting, was also initiated. As of March 24, 1972, 44 active dialysis centers were treating 806 patients on hemodialysis, and 44 on peritoneal dialysis; an additional 1973 patients were in home training, and another 766 were dialyzing at home; 26 patients were being treated in satellite centers; and there were 111 "contract" patients being treated in non-VA centers but financed by the VA. Kidney transplantation was begun as early as 1962 by Dr. Thomas Starzl, in Denver, and by 1971 the VA was averaging about 150 to 175 transplants per year.

elsewhere in the body, or by unknown factors. The commonest form of interstitial disease is caused by infection in the kidney (pyelonephritis) or is secondary to analgesic abuse. Polycystic kidney disease is congenital.

Richard A. Rettig, "Lessons Learned from the End-Stage Renal Disease Experience," in Richard H. Egdahl and Paul M. Gertman, eds., Technology and the Quality of Health Care, Germantown, Maryland, Aspen Systems Corporation, 1978, pp. 153-173. See Patrick T. McBride, Genesis of the Artificial Kidney, Travenol Laboratories, Inc., 1979, for an excellent analysis of the development of hemodialysis technology.

Richard A. Rettig, "The Policy Debate on Patient Care Financing for Victims of End-Stage Renal Disease," Law and Contemporary Problems, Vol. 40, Autumn 1976, pp. 196-230.

Within the Public Health Service (PHS), the National Institutes of Health supported research efforts. In 1964, in response to the earlier clinical recognition that immuno-suppressive drugs could help control host rejection of a transplanted kidney, Congress established a program in transplant immunology within the National Institute of Allergy and Infectious Diseases. The following year, it established the artificial kidney program within the National Institute of Arthritis and Metabolic Diseases to improve the technology of hemodialysis. Also established within the PHS was the "kidney disease control program" (KDCP). Organized initially within the Bureau of State Services, this program survived several name changes and reorganizations of its parent agency. It funded 14 community dialysis demonstration projects, supported a dozen home dialysis demonstrations, and helped establish regional organ acquisition and tissue typing capabilities for transplantation. After transfer into the Regional Medical Programs Service (RMPS) in 1969, the program funded the development of dialysis treatment capacity across the country and emphasized a regional approach to the provision of services. By early 1973, however, the RMPS was in the throes of a prolonged bureaucratic death; the KDCP expired with it.

The program developments within the VA and the PHS prompted a high-level policy review in the mid-1960s. A committee of experts was established by the Bureau of the Budget in 1966 to analyze the implications for the federal government of the development of hemodialysis and transplantation. The committee's report, released in the fall of 1967, recommended that a national treatment benefit program be established by amending Title XVIII of the Social Security Act to cover

Although this program did change names several times, we refer to it consistently as the KDCP.

These events are analyzed in Richard A. Rettig, "Formal Analysis, Policy Formulation, and End-Stage Renal Disease," a paper prepared for the Office of Technology Assessment, forthcoming in a volume of papers on cost-effectiveness analysis in health, 1980.

end-stage renal disease victims. Although quietly released, this report was widely read. Several proposed bills incorporated its major recommendations, but no legislation was enacted. This was partly due to the simultaneous release of a PHS report that emphasized research and prevention rather than treatment and reinforced more general efforts to dampen interest in a treatment benefit program. 2

Not until the 1970 reauthorization of the Heart Disease, Cancer, and Stroke Amendments, when "kidney" was added to this statute's title, was any "kidney" legislation enacted. Two years later, however, Congress included Section 299I in the Social Security Amendments of 1972, thus establishing the end-stage renal disease program of Medicare.

Section 299I of Public Law 92-603

The policy authorizing the ESRD program had lengthy antecedents, described above, but a brief legislative history. In early 1971, at the outset of the 92nd Congress, the Nixon administration proposed a number of major amendments to the Social Security Act. The bill which was introduced in the House of Representatives as H.R. 1 dealt with consolidation of 54 federal-state programs for the needy aged, blind, and disabled; the establishment of more effective cost controls for Medicare and Medicaid; the provision of health care to Medicare and Medicaid recipients through health maintenance organizations; and

¹U.S. Bureau of the Budget, Report of the Committee on Chronic Kidney Disease, Washington, D.C., September 1967.

Department of Health, Education, and Welfare, *Kidney Disease*, *Program Analysis*, A Report to the Surgeon General, Washington, D.C., 1967.

This section draws extensively upon Rettig, "The Policy Debate on Patient Care Financing for Victims of End-Stage Renal Disease," Law and Contemporary Problems, Vol. 40, No. 4, Autumn 1976, especially pp. 222-225.

various modifications of the Social Security benefit structure. ¹
But "by far the most significant and the most needed provisions of
H.R. 1," in the words of Elliott Richardson, then Secretary of Health,
Education, and Welfare, were "those which reform the family welfare
system and replace it with a new national program."²

The welfare reform debate was protracted, especially in the Senate. In addition to the Nixon administration's proposal, Senator Russell B. Long (D., Louisiana), chairman of the Finance Committee, was advocating a more conservative welfare reform bill, while Senator Abraham Ribicoff (D., Connecticut) was proposing a more liberal version. None of the three parties had the votes to prevail over the other two, nor were any two able to compromise differences. By midsummer 1972, it was clear that welfare reform legislation had effectively been killed.

The prolonged debate on welfare reform consumed so much time that passage of any bill was threatened. Since H.R. 1 contained many other important provisions, no one wished the Congress to fail to enact legislation. A commitment to pass some bill was reinforced by the desire to avoid the experience of 1970, when the House refused to meet with the Senate because there was so little time to negotiate important differences before the November election. This time, both House and Senate were determined to have legislation on the President's desk before election day, November 7, 1972.

At no point in the extensive hearings on H.R. 1 did either the House or the Senate hear testimony on renal disease. It is true, however, that in November 1971 the House Ways and Means Committee, in

See U.S. Senate, Committee on Finance, Social Security Amendments of 1972, S. Report No. 92-1230, 92nd Cong., 2nd sess., September 26, 1972, for the bill as it came to the Senate floor.

²U.S. Senate, Committee on Finance, Social Security Amendments of 1971, Hearings, Part 1, p. 30, 92nd Cong., 1st sess., 1971.

Interview with Irwin Wolkstein, Bureau of Health Insurance, Social Security Administration, Baltimore, Maryland, September 10, 1973.

connection with hearings on national health insurance, heard testimony urging that end-stage renal disease be included in any such program. It was on this occasion that Shep Glazer, a dialysis patient and representative of the National Association of Patients on Hemodialysis and Transplantation, was dialyzed in the hearing room before the members of the Ways and Means Committee. Following this, in December, Representative Wilbur Mills (D., Arkansas), committee chairman, introduced a bill to amend the Social Security Act and provide patient-care financing for chronic renal disease patients. 2 It was a bill more notable for signaling Mr. Mills's intentions than for the care with which it was drafted. His larger intentions, in fact, were made much clearer in early 1972 when he announced his candidacy for the Democratic nomination for the presidency. But neither the Ways and Means Committee hearing nor Mills's legislative proposal was part of the legislative history of H.R. 1. Furthermore, there was no activity within the Senate Finance Committee during this time that remotely related end-stage renal disease to H.R. 1.

The end-stage renal disease amendment to H.R. 1 was never considered until the provisions of the entire bill were being debated seriatim on the Senate floor. On Saturday morning, September 30, Senator Vance Hartke (D., Indiana) proposed an amendment on chronic renal disease, which was adopted after 30 minutes of discussion. The joint conference committee of the House Ways and Means Committee and the Senate Finance Committee, on a Saturday evening two weeks later, shortened the eligibility waiting period from six months to three months and adopted the provision after ten minutes of discussion. The provision became simply one more part of an already complex bill, which President Nixon signed on October 30, 1972.

¹U.S. House of Representatives, Committee on Ways and Means, *National Health Insurance Proposals*, Hearings, Part 7, pp. 1524-1546, 92nd Cong., 1st sess., 1971.

²See H.R. 12043, 92nd Cong., 1st sess., 1971.

³Public Law 92-603, the Social Security Amendments of 1972, is 165 pages long. It contains numerous amendments to the old-age survivors, and disability insurance program and to the Medicare, Medicaid, and maternal and child health programs. One major change in

Congress had extended Medicare coverage to victims of a specific categorical disease with very little discussion, thus bequeathing to itself the basis for questioning time and again the wisdom of its action. But Congressional intent at the time was relatively clear. The amendment was to provide access to life-saving therapy for all who needed it where the costs of treatment were beyond the means of practically all individuals. As Senator Hartke, sponsor of the amendment, said:

In what must be the most tragic irony of the 20th century, people are dying because they cannot get access to proper medical care. We have learned how to treat or to cure some of the diseases which have plagued mankind for centuries, yet these treatments are not available to most Americans because of their cost. . . . Mr. President, we can begin to set our national priorities straight by undertaking a national effort to bring kidney disease treatment within the reach of all those in need.1

In providing access, the underlying rationale was to resolve the "tragic choice" between the allocation of scarce resources and the value of human life. As Hartke put it, the fundamental question was this: "How do we explain that the difference between life and death is a matter of dollars? How do we explain that those who are wealthy have a greater chance to enjoy a longer life than those who are not?" Echoing this view, Senator Henry Jackson (D., Washington) said:

I think it is a great tragedy, in a nation as affluent as ours, that we have to consciously make a decision all over America as to the people who live and the people who will

Medicare, for instance, extended coverage to the disabled, while another provided for professional standards review organizations (PSROs). One of the most significant changes was Title III of the Act, which established the Supplemental Security Income (SSI) Program for the aged, blind, and disabled, thus "federalizing" state welfare programs in the adult public assistance categories.

¹118 Cong. Rec. 33003 (1972).

²Ibid.

die. We had a committee in Seattle, when the first series of kidney machines were put in operation, who had to pass judgment on who would live and who would die. I believe we can do better than that. . . . So I would hope that we would make an effort here, at least a beginning, to approve the amendment, so that we can do better than we have done heretofore. 1

Senator Chiles (D., Florida), honorary chairman of the Florida Kidney Foundation, Inc. that year, repeated a similar point: 2

. . . in this country with so much affluence, to think that there are people who will die this year merely because we do not have enough of these machines and do not have enough dollars, so that we do have to make the choice of who will live and who will die, when we already know we have a good treatment that can succeed and keep these people alive, while we are working out other improvements in transplants, finding cures, and everything else necessary. This should not happen in this country.

Significantly, the reluctance to sacrifice lives for dollars was not articulated as an absolute value, but as one that bore some relation to national wealth or affluence.

Still, proponents of the amendment were not indifferent to the costs of treatment. Senators Hartke, Jackson, and Magnuson (D., Washington) all suggested that the costs of dialysis would continue to go down with new advances in technology. Hartke also argued for kidney transplantation in glowing terms and looked forward to substantial cost reductions for this surgical procedure. Costs of dialysis, moreover, could be offset in Hartke's view by the prospect that 60 percent could return to work with retraining while "most of the remaining 40 percent need no retraining whatsoever." In short, there was reason to be optimistic about cost.

¹Ibid., 33007.

²Ibid., 33008.

³Ibid., 33004.

Only Senator Wallace Bennett (R., Utah) opposed the amendment. He thought the Senate was about to vote \$100 million to \$250 million for dialysis and transplantation. He argued that the amendment, like others added the previous day, represented "Christmas in September" and was "an additional straw that will break the back of the social security system." Bennett also argued that the amendment was the "wrong vehicle." Kidney disease was being singled out for special treatment. "A more reasonable way to handle this amendment," the Utah Republican argued, "would have been to delay action until it can become part of a broader health insurance bill."

Senator Long, floor manager of H.R. 1 as chairman of the Senate Finance Committee, responded to Bennett's last argument. 3

The next Congress will tackle health insurance issues, and I am sure during that debate we will deal with health insurance problems in general, and I hope that specifically we will deal with the problem of insuring against catastrophic illness. I am cosponsoring this proposal at this time because these very unfortunate citizens with chronic renal failure cannot wait for Congress to debate these broader issues. They need help—it is critical—and that help must come now as many of them, without assistance, simply will not be alive for another two years.

The medical means to deal with end-stage renal disease were at hand. Under such circumstances, one should not pass up the legislative opportunity to act.

The Bureau of Health Insurance of the Social Security Administration carefully followed the development of amendments to the Medicare statute as H.R. 1 moved through the legislative process in 1971 and 1972. The inclusion of Section 299I in the bill, however, caught them by surprise. But by working with Senate Finance Committee staff, BHI officials were able to secure the following statement by Senator Long on the day of final Senate passage of the bill:

¹Ibid., 33008.

²Ibid.

³Ibid., 33009.

⁴118 Cong. Rec. 36805 (1972).

With respect to the coverage of kidney dialysis and transplantation, the Secretary would have the authority to define reasonable charges in terms related to the reasonable costs of the treatment provided and comparable charges for physicians' time and skills, since obtaining customary and prevailing charges for new and complex procedures—many of which will be reimbursed in all instances by the program—would be quite difficult administratively.

The Senator's statement clearly pointed toward cost containment to those familiar with the language of government health care financing. It established the basis for significant Medicare policy departures in the reimbursement of ESRD treatment and proved critical on several later occasions in the implementation of the program.

Section 299I represented a major extension of Medicare coverage, providing benefits on a near-universal basis to victims of a particular disease. Medicare entitlement was established for individuals under 65 years of age, who are "fully or currently insured" or "entitled to monthly insurance benefits" under the Social Security Act, or who are the spouses and dependent children of insured individuals, if the individual is "medically determined to have chronic renal disease" and requires hemodialysis or renal transplantation to live. Eligiblity was to begin "with the third month after the month in which a course of renal dialysis is initiated" and would end with the twelfth month after a transplant or after dialysis treatment had been terminated. Individuals meeting these criteria, the statute declared, "shall be deemed to be disabled for purposes of coverage

The complete provision is found in Appendix A.

The coverage of kidney failure does not include, for instance, federal government employees who have too few accumulated quarters of contributions to Social Security to be "fully or currently insured," or those who have not contributed to Social Security. The exact magnitude of the noncovered is not known, though it is estimated at less than 10 percent of the U.S. population. The Congress directed the HEW Secretary to conduct a study of the number of uncovered individuals.

under parts A and B of Medicare subject to the deductible, premium, and copayment provisions of Title XVIII."

The statute conveyed broad discretion to the Secretary of Health, Education, and Welfare "to limit reimbursement under Medicare for kidney transplant and dialysis to kidney disease treatment centers which meet such requirements as he may by regulation prescribe."

Within this delegation, the Secretary was required to include "a minimal utilization rate for covered procedures" and "a medical review board to screen the appropriateness of patients for the proposed treatment procedures." This latter provision was an explicit statement of legislative concern for quality of care.

What emerges from the legislative history of Section 299I, therefore, is a *goal structure* for the ESRD program consisting of the following objectives:

- o To provide access to ESRD medical services, both dialysis and transplantation, to all those individuals eligible to receive such services;
- o To insure the high quality of delivered services; and
- o To contain the total program costs.

Even though the statute authorizing the ESRD program was amended in 1978, the goal structure was unaffected, and Section 299I and its legislative history constituted the basis for policy well into 1979.

THE ORGANIZATION OF THE PROGRAM

Here we indicate the implementation problem structure for both the interim and long-term programs and provide a chronology of major events.

 $^{^{1}}$ Public Law 95-292, June 13, 1978, 95th Cong. (H.R. 8423).

The Interim Program

The regulations published on June 29, 1973, establishing the framework for implementing the ESRD program, were clearly designated as interim. This implied a temporary state, but the policies established at that time, with the exception of a 1974 modification of physician reimbursement policy, remained in effect well into 1979. In fact, the regulations implementing P.L. 95-292, amending legislation enacted on June 13, 1978, were only issued in late 1979 and 1980 to supplant the original interim regulations.

The interim program, by virtue of the issues it addressed, acquired a substantive meaning focused primarily upon reimbursement issues. The implementation problem structure for the interim program consisted of the following elements:

- o Patient eligibility and entitlement;
- o Facility qualification or certification;
- o Facility reimbursement;
- o Physician reimbursement;
- o Home dialysis; and
- o Claims processing.

In the next two sections, policy planning, operational planning, and policy design in the operations stage are analyzed with reference to these elements.

The chronology of major events of the interim program is indicated in Table 5. These events focus mainly on the publication of basic policy statements governing reimbursement.

The Long-Term Program

Describing the initial ESRD program as interim led to the use of long-term to refer to that which would follow it. But long-term, like interim, also acquired a more substantive meaning, concerned primarily with the organization of the ESRD delivery system.

The Final Policies of April 1974 addressed both the interim and long-term programs, and dealt substantively with both reimbursement

Table 5
CHRONOLOGY OF MAJOR EVENTS OF THE ESRD INTERIM PROGRAM

Date	Event
10-30-72	P.L. 92-603 enacted
6-29-73	Interim regulations published
7- 1-73	Effective date of ESRD program
12-14-73	Facilities exceptions criteria and procedures distributed; proposed rule published, 10-4-74; final rule published, 4-22-75
4-17-74	Final policies announced
11- 9-76	Subpart E proposed regulations published; final rule published, 12-30-77
6-13-78	P.L. 95-292 enacted

and organizational issues. But this was the only occasion when all issues were considered at the same time. For analytical purposes, it makes sense to regard the interim program as occupied with reimbursement issues and the long-term program with organizational matters.

The implementation problem structure for the long-term program consisted of the following elements:

- o Minimum utilization rates for covered services;
- o Medical review boards;
- o ESRD networks; and
- o An ESRD Medical Information System (MIS).

The policy and operational planning for these elements will be analyzed in Sections VI and VII.

The chronology of major events in the long-term program is shown in Table 6.

THE ADMINISTRATIVE SYSTEM

Implementation occurs primarily in an administrative context.

In this subsection, therefore, we delineate the administrative system

Table 6

CHRONOLOGY OF MAJOR EVENTS OF THE ESRD LONG-TERM PROGRAM

Date	Event
4-17-74	Final policies announced
7- 1-75	Subpart U proposed regulations published
5- 3-76	Subpart U final regulations published
8-29-77	Network funding decision announced

for the ESRD program, identifying the major organizations and administrative subsystems and suggesting some of the dynamic interactions between these organizations.

Members

Which officials and organizations are members of the ESRD administrative system? Let us begin with the Secretary of Health, Education, and Welfare, in whom Congress has vested authority for the program and within whose department it is administered. The Secretary is involved as is the Office of the Secretary. The latter includes the offices of the Under Secretary and of the general counsel, and those of the assistant secretaries for legislation, management and budget, planning and evaluation, and, in this instance, health.

For the ESRD program, the Office of the Assistant Secretary for Health, or "H" as it is called, has been the most important unit in the Office of the Secretary. By contrast, for the larger issue of national health insurance, the Office of the Assistant Secretary for Planning and Evaluation dominated HEW policy development, though H played an important contributing role.

Six health agencies report to the Assistant Secretary for Health: the Alcohol, Drug Abuse, and Mental Health Administration (ADAMHA); the Center for Disease Control (CDC); the Food and Drug Administration (FDA); the Health Resources Administration (HRA); the

Appendix B contains several pertinent organizational charts.

Health Services Administration (HSA); and the National Institutes of Health (NIH). The primary actor in the ESRD program is HSA, through a renal unit in the Bureau of Quality Assurance (BQA). In a broader sweep than analyzed here, however, lesser roles in renal disease are played by CDC, FDA, HRA, and NIH. 1

The health financing agency, as distinct from health agencies, from 1972 until May 1977, was the Social Security Administration (SSA) and its Bureau of Health Insurance (BHI). Also involved within SSA, however, were the Office of the Actuary, the Office of Research and Statistics, and the Bureau of Data Processing. Within BHI, the key units were the Office of the Deputy Director for Program Policy, and its Division of Provider and Medical Services (which came to house a shadow policy group for renal), the Office of the Deputy Director for Program Operations, and its Division of State Operations, and the Office of the Assistant Director for Central Operations, with its Division of Special Operations. The Chronic Renal Disease (CRD) unit was located within Special Operations, though the latter tended to be moved about within the BHI framework.

In May 1977, the Health Care Financing Administration (HCFA) was created, combining in one organization the responsibility for both Medicare and Medicaid (which had previously been administered by the Medical Services Administration of the Social and Rehabilitation Service). BHI was removed from SSA and renamed the Medicare Bureau of HCFA. BQA was similarly removed from HSA and renamed the Health Standards and Quality Bureau (HSQB) of HCFA. In mid-1979, HCFA reorganized, and since then organization for renal disease has been in flux.

Beyond the central office organizations of SSA and BHI and, subsequently, HCFA Medicare, lies a decentralized administrative blanket covering all U.S. states and territories. A certain number of

¹In ADAMHA, the National Institute of Mental Health currently is supporting controlled clinical trials to determine whether dialysis is effective treatment of schizophrenia. But this effort has nothing to do with the ESRD program.

functions are performed by the SSA office in each of the ten HEW regional offices. The SSA district and branch offices, of which there are approximately 3,500, initiate the enrollment of patients as beneficiaries. The financial intermediaries and financial carriers are private organizations who contract with the government to administer claims processing for Medicare for Parts A and B, respectively. Typically, one intermediary and one carrier exist for each state, though there are several for some of the larger states. Certification of ESRD facilities used to begin with an application submitted by the treatment facility to a local Comprehensive Health Planning "B" agency, transmitted to the BHI regional office, then sent upward through the system. Today a new application is sent through the ESRD network, the local HSA successor to the CHP "B" agency, then to the statewide health planning authorities, and the HCFA regional offices. Since 1977, however, recurring annual certification is done by state survey agencies, attached to state departments of public health, funded by Medicare, and linked to the successor to BHI's Division of State Operations. Medical review is performed by the ESRD networks' medical review boards; these boards, moreover, have formal written arrangements with the relevant PSROs.

Are patient beneficiaries, physicians, and treatment facilities part of the administrative system? The question can be argued both ways. Patients are those for whom the system exists and they interact with it for only part of their lives. As autonomous human beings they (and not the system) determine what lives they shall lead. They receive the system's benefits but are not cogs in its machinery. On the other hand, given their terminal disease state, they are utterly dependent upon the system for the continuance of life. And the undertow of the system carries many patients beyond medical dependence to economic dependence on monthly disability benefits, thus severely reducing their autonomy. Still, the system exists for them—indeed, it derives its moral justification from meeting their needs—and not they for the system.

Physicians have a more complex relationship to the administrative system. Highly trained professionals, they have specialized in an

area of medicine dominated, for all practical purposes, by the state. Although not technically government employees, they nevertheless bargain with it about how and for what they will be paid and, to some degree, about how they will treat their patients. (Their situation is not unlike members of a labor union bargaining with an employer about wages, hours, and conditions of work.) As long as they choose to treat patients by dialysis or transplantation, physicians have autonomy of professional action only within constraints set by the government. They are integral and essential to the functioning of the system, though they would probably argue their autonomy from it on legal grounds.

Treatment facilities also have a legal status conferring the appearance of autonomy, though they are also integral and essential to the administrative system. Facilities are regulated on utilization rates, health and safety standards, personnel staffing patterns and standards, cost accounting, governance, and reimbursement. Facilities do exercise discretion within these regulatory constraints, but if the ESRD program disappeared, so would the majority of treatment facilities.

The above list of organizations may be exhausting, but it is not necessarily exhaustive. Substantially greater detail could be provided on each of the agencies. Moreover, other organizations not identified here do occasionally become involved with ESRD matters in ways understandable at the time but not necessarily predictable in advance.

In sum, what we have tried to indicate here is that the administrative system is a complex, interorganizational network, encompassing a number of federal agencies (at both central and field office

¹Interesting evidence on this point is provided by National Medical Care, Inc., a Boston-based, for-profit firm under whose auspices one-fifth of the nation's patients are being dialyzed. Although constantly touting the virtues of the private, for-profit sector in delivering dialysis services, they recently reassured their stockholders in this way: "Recent severe increases in the prime rate of interest and threats of an economic recession will not materially affect the Company's operations as none of the Company's debt is subject to prime rate fluctuations, and our business operations are not

locales), state government agencies, regional entities (including those "dedicated" to renal as well as more general-purpose organizations), private claims processing agencies, and treatment facilities including public, private, nonprofit, and private, for-profit organizations. And different subsystems of the overall system are activated for the different functions of patient enrollment, claims processing, facility certification, and medical review.

Basic Resources

Two basic resources of the administrative system are of concern to us: authority—the legal obligation and right to administer, and money—that which can be transformed into the production and delivery of desired services.

The authority to administer the programs authorized by the Social Security Act, including the Medicare program, is vested by law in the Secretary of Health, Education, and Welfare. The Secretary, in turn, has redelegated this authority to the Commissioner of Social Security, who exercised it through the Bureau of Health Insurance of SSA. The creation of HCFA in 1977 resulted in a redelegation of authority from the Commissioner to the Administrator of HCFA for the administration of Medicare. Because the ESRD program amended the Medicare statute, it became the administrative responsibility of the Commissioner, thus of SSA, and thence of BHI, under the general delegation of secretarial authority. This delegation has been a residual source of power for BHI.

The Secretary of HEW has also delegated broad general authority to the Assistant Secretary for Health pertaining to "all health-related

affected to any great degree by outside economic conditions." National Medical Care, Inc., Third Quarter Report, September 30, 1979. Legal autonomy coexists with financial dependence.

¹See 33 Federal Register 5836, April 16, 1968.

²42 Federal Register 32845, June 28, 1977.

activities in the Department." Specifically, the delegation provides that:

He is responsible for the direction of the health agencies of the Department, for providing leadership and policy guidance for health-related activities through the Department, and for maintaining relationships with other governmental and private agencies concerned with health.

Late in the first Nixon administration and early in the second, this general authority for "policy guidance" was reinforced by political support for greater H involvement in Medicare than had previously been the case.

The authority of the ESRD unit in HSA and BQA was derived both from SSA and BHI and from the Assistant Secretary for Health. Historically, BHI has relied upon the Public Health Service for professional advice and consultation on medical matters confronting Medicare. This historic relationship constituted one source of authority for BQA involvement in the ESRD program. From the Assistant Secretary for Health, BQA received designation as the logical health agency to develop ESRD networks, due in part to the formal delegation of authority to BQA for administering the related PSRO program.

In 1974, an "allocation of responsibilities" was negotiated between BHI and BQA for the ESRD program, with the former being primarily responsible for reimbursement issues and the latter for medical issues. This mutual agreement, however, was not a formal delegation of authority, which could come only from the Secretary, and its operational significance was never entirely clear. The agreement was a charter providing BQA a role, but it did not convey authority to act.

¹37 Federal Register 24377, November 16, 1972.

²Memorandum, from Administrator, HSA, to Director, Bureau of Health Insurance, SSA, "BHI/BQA Allocation of Responsibilities and Implementation--ACTION," April 17, 1974. Signed by Harold O. Buzzell, HSA Administrator, the memorandum was concurred in by Thomas Tierney, BHI Director.

With respect to financial resources, the ESRD program is financed through a trust-fund arrangement, as are many entitlement programs, and not through the annual appropriations process. Medicare revenues are raised by the Social Security payroll tax for the hospital insurance portion of the program—Part A, administered by the Hospital Insurance Trust Fund, and by a combination of enrollee premiums and general revenues for the supplementary medical insurance portion of the program—Part B, administered by the Supplementary Medical Insurance Trust Fund. Trust fund financing has been a continuing source of power for BHI in implementing the ESRD program.

The Organizational Response to the ESRD Program

Until the creation of HCFA, three organizations were primarily involved in implementing the ESRD program—the Office of the Assistant Secretary for Health; the Bureau of Health Insurance of SSA; and the ESRD unit of HSA and BQA.

During the period covered by this study, H had three assistant secretaries -- Drs. Charles C. Edwards, Theodore Cooper, and Julius B. Richmond. The principal staff professional dealing with ESRD questions was Dr. Ronald M. Klar. The ESRD involvement of H was a matter of discretionary choice, motivated partly by the neglect of this matter by the Assistant Secretary for Planning and Evaluation, partly by Klar's personal desire to stake out a role for H, and partly by the supporting acquiescence of both Edwards and Cooper. Involvement by H, as we shall see, did not begin until several months after the legislation had been passed and came because of Klar's dissatisfaction with the estimates used in the Senate debate to justify Section 2991. Although concerned with the full range of reimbursement issues, Klar focused the attention of the Assistant Secretary on the long-term ESRD program, and especially on issues of network organization. The high point of Klar's involvement came, as discussed below, with the issuance of Final Policies in April 1974.

The trustees of both funds are the Secretaries of Treasury, Labor, and Health, Education, and Welfare.

BHI was the second major organization involved with the program, an obligatory involvement by virtue of it being part of Medicare. Within BHI, control over early ESRD policy was exercised by the Deputy Director for Program Policy, Irwin Wolkstein, and his assistant, Robert Smith, a result of both bureaucratic logic and personal choice. BHI, while Congress considered H.R. 1, established task forces to study each of its major provisions. The sudden inclusion of Section 299I in the final bill surprised BHI. Though it had responded to a few inquiries about end-stage renal disease during 1971 and 1972, and though the rudiments of a policy were emerging from these responses, the scale and scope of planning and operational questions posed by the ESRD program carried the organization from extremely limited involvement with kidney disease to near-total immersion within a short time.

BHI responded to Section 299I by creating a work group from key units in the organization--policy, systems, state operations. Wolkstein exerted control over policy, but state operations, as we shall see, responded to the new initiative in a way consistent with its previous activities and function within the Medicare program. The general delegation of secretarial authority for Medicare and trust fund financing made SSA and BHI, and later HCFA, the dominant organization in implementing the ESRD program.

Wolkstein exercised the primary role in BHI until his retirement from government service in 1975, but none of his successors showed the same interest in the program. Within the Office of Program Policy, there evolved a "shadow" renal group in the Division of Provider and Medical Services Policy headed by Milton Cikins, a member of the original BHI work group, to handle reimbursement, coverage, and entitlement issues, including the development of implementing regulations. For operations, BHI created a new Chronic Renal Disease (CRD) branch, headed by Phil Jos, to manage the ESRD program. The "shadow" policy group and the CRD branch worked out relationships to link policy and operational decisions. CRD, in turn, established relationships with the SSA and BHI regional and district offices,

fiscal intermediaries and carriers, providers and nonprovider facilities, and physicians.

Parenthetically, before discussing the third major organization, we note an organization fading from the scene as the ESRD program was beginning. Within PHS existed the Kidney Disease Control Program of the Regional Medical Programs Service (RMPS). Since 1965 this organization had been the principal PHS unit responsible for health service delivery for end-stage renal disease. It funded demonstrations of both center and home dialysis, as well as organ procurement and tissuetyping information systems. A special irony faced the KDCP in late 1972: as the government was on the threshold of financing ESRD patient care, this organization (and its parent) were slated for bureaucratic death. As it expired, the KDCP provided information, comments, and staff memoranda to the two more significant bureaucratic actors. We also note that the two research programs of the National Institutes of Health--in the arthritis and the allergy institutes--continued to function. The primary NIH contribution to the ESRD program though was to continue support for the National Dialysis Registry and the Human Renal Transplant Registry.

The third organization was in the Health Services Administration. In early 1973, the Health Services and Mental Health Administration, which included the RMPS and its KDCP, was reorganized. HSA emerged from the reorganization as a new agency within which the Bureau of Quality Assurance had primary responsibility for implementing the PSRO program. Initially within BQA's Division of Medical Care Standards, then in the Division of Peer Review, an end-stage renal disease unit was created. "Created" may be too strong a verb, because the unit never had more than a tenuous toe-hold on the bureaucratic mountainside. Although it existed until well after the transfer of BQA to HCFA in May 1977, this unit never had a formal designation within BQA, never received a specific allocation of personnel positions, never had a line item budget, and had four directors from 1973 until its demise in 1978.

BQA was headed by Dr. Michael Goran from 1973 through 1977. The ESRD unit was successively headed by Dr. Samuel Kidder (1973), a

career government employee, Dr. Alvin Goodman, a nephrologist on leave in 1974 from his medical responsibilities in Westchester County, New York, Dr. Thomas Murray (1975-1976), a physician fulfilling a two-year Public Health Service tour of duty, and Royal Crystal (1976-1978), a career government employee. Goodman, in particular, was a forceful individual, partly because of personality and partly because of his professional independence from the bureaucracy. He made a number of important policy contributions during his one-year tour: with Klar and Wolkstein, he developed the basis for the Final Policies; with Wolkstein, he negotiated the BHI-BQA allocation of responsibilities; he catalyzed the Medicare-Veterans Administration agreement of 1974; and helped design the ESRD networks.

But Goodman, his predecessor, and his successors, faced continual resistance and opposition over this entire time from Dr. Michael Goran, the BQA director. The financial and personnel commitments wrung out of an incumbent assistant secretary from time to time, were effectively thwarted by Goran since their realization would mean reallocating money and positions away from his PSRO responsibilities. Klar, for all his policy concerns, was either unwilling or unable to see that H commitments were realized for the ESRD unit. Nor was the matter of high priority for either Edwards or Cooper.

Among these three organizations, there was a controversy between H and BHI over reimbursement issues, with BQA and ESRD playing a minor role. Policy for medical or organizational issues was developed mainly by H, with strong BQA and ESRD involvement and a passive response by BHI. Between BHI and BQA, the former clearly dominated reimbursement issues, and because of its delegated authority and trust fund financing, could sometimes play a role of passive resistance on organizational issues.

Organizational Dynamics

Planning for the ESRD program involved these three organizations, and the interactions among them contributed strongly to the

¹Klar and Goodman thoroughly disliked each other, while Goodman and Wolkstein got on well together.

dynamic of the implementation process. Two motifs dominated these interactions during the first half of 1973—discontinuity and conflict. Discontinuity was apparent as the KDCP passed from the scene and as BHI and H rapidly became involved with ESRD implementation. The medical community, long involved with the KDCP—as recipient of its grants and contracts and as the giver of policy and program advice—had very limited experience with BHI and with H. Discontinuity applied to bureaucracies, personnel, advisory relations, and operating assumptions. P.L. 92-603 had rearranged the physician's relations to the federal government.

Conflict emerged from several sources. Throughout the first Nixon administration (1969-1972), for instance, the White House and more than one HEW secretary chafed at their inability to control Social Security Commissioner Robert Ball. This was simply one more instance of the Nixon administration's profound distrust of the federal bureaucracy, which was perceived as staffed by liberal, Democratic careerists. After the President's landslide reelection victory in November 1972, however, Ball was among the many senior federal government officials whose "resignation" was accepted by the Administration. 2

Closely related was the effort by several assistant secretaries for health to exert greater departmental control over Medicare, beginning with Dr. Merlin DuVal, in 1971, and continuing through Edwards. This effort was stimulated by the prospect of enactment of major national health insurance legislation and represented advance skirmishing for control of such an initiative. During Edwards' tenure, two specific conflicts included the assignment of responsibility for PSROs to the Health Services Administration, rather than SSA and BHI,

¹ See M. Derthick, *Policymaking for Social Security*, Washington, D.C., The Brookings Institution, 1979, esp. pp. 345-349, for a discussion of the unwillingness of the Republicans to replace Ball with someone more to their liking.

²Dr. Robert Q. Marston, Director of NIH, and Dr. Vernon Wilson, Administrator of HSMHA, also lost their jobs at this same time.

and control by H over health care financing research authorized by Section 222 of P.L. 92-603.

Finally, conflict emerged from differing views of policy. Policy as understood by H was primarily seen as the exercise of discretion by the HEW secretary. Specific statutory directions were not always followed and sometimes were simply ignored. Discretion was often seen as an unrestricted opportunity for action. Secretarial policy was formally expressed in action memoranda to which the Secretary affixed his signature, in statements by him to the public, and in federal regulations. Policymaking was managed by staff in the Office of the Secretary, who drafted the memoranda, sought comments on such drafts, revised them, and then secured higher level approval from the Secretary for a given policy option. Interaction between the Office of the Secretary and departmental bureaus was where issues were defined and options developed, but high-level meetings of senior departmental officials were the arena within which unresolved questions were thrashed out and policy decisions made. Once a Secretarial policy decision had been reached, it was assumed that subordinate agencies would carry it out.

In this context, Assistant Secretary for Health Charles C. Edwards had a close personal relationship with HEW Secretary Caspar Weinberger, plus delegated authority as "the principal advisor and assistant to the Secretary on health policy and all health related activities in the Department." Klar functioned as Edwards' principal staff aide on ESRD policy issues.

Policy for SSA and BHI differed from H in certain important respects. It is conceived as the exercise of administrative discretion in fulfilling the intent of Congress as expressed in the Medicare statute. This discretion sometimes requires the direct involvement of the HEW Secretary, but often is exercised at the SSA or even BHI level. Statutory directives are to be fulfilled and discretion to be exercised consistent with existing Medicare statute law

¹37 Federal Register 24377, November 16, 1972.

and regulations and with reference to ease of administration by the federal government, fiscal intermediaries and carriers, providers, suppliers, and physicians. The formal expression of policy is typically through federal regulations, but also includes intermediary letters, manuals, and other documents containing the words by which others finally have to live. Policymaking is managed largely by BHI, in conjunction with officials in SSA and the Office of the HEW Secretary, with basic documents being developed at the BHI staff level. The arena of policymaking is sometimes high-level departmental meetings, often meetings between departmental and bureau officials, and not infrequently the bureau level only. Policy, though separate from operations, is developed with appreciation of, if not in concert with, operational considerations and is thus sensitive to problems of implementation.

Also important in institutional and personal terms was the fact that strong relations existed between individuals in SSA and BHI and the key members and staff professionals of the House Ways and Means Committee and the Senate Finance Committee. Relations between individuals in BHI and those in the Office of the Secretary involved fewer long-standing personal associations, were subject to changes of political appointees, and sensitive to the ideological and idiosyncratic disposition of the individuals.

Conflict between BHI and H, then, as it played out over time, arose from competition for organizational control, jockeying for position in the event of expansion of national health insurance, differing views of the policy process, some genuine issues of substance, as well as from the personalities involved. These differences are set forth in greater detail in the following pages.

Two other features—personnel turnover and bureaucratic reorganization—reveal the dynamic character of the administrative system. The following table shows the turnover among some HEW officials—from the HEW Secretary to program administrators. One pattern revealed is the constant coming and going of the Secretary, Under Secretary, and Assistant Secretary for Health. Another is the departure—via firing or resignation—of career civil servants in SSA

Table 7

TENURE OF HEW OFFICIALS AFFECTING THE ESRD PROGRAM, 1972 TO THE PRESENT

Secretary of Health, Education, and Welfare Elliott L. Richardson	From	6-24-70 to	1-29-73		
Caspar W. Weinberger David Mathews Joseph A. Califano, Jr. Patricia R. Harris		2-8-73 8-11-75 1-25-77 8-3-79	8-10-75 1-20-77 8-8-79 present		
Under Secretary of Health, Education, and Welfare					
Frank C. Carluci Marjorie W. Lynch Hale Champion Nathan Stark		2-2-73 11-9-75 4-3-77 11-2-79	12-25-74 1-20-77 6-3-79 present		
* * *	*				
Assistant Secretary for Health					
Merlin K. Duval Charles C. Edwards Theodore Cooper Julius B. Richmond		7-1-71 4-18-73 7-1-75 7-2-77	12-15-72 6-21-75 1-20-77 present		
* * *	*				
Commissioner of Social Security					
Robert M. Ball Arthur E. Hess (Acting) James B. Cardwell Stanford G. Ross		4-62 3-17-73 10-14-73 10-2-78	3-16-73 10-13-73 12-12-77 present		
Director, Bureau of Health Insurance, SSA					
Thomas M. Tierney		4-67	3-77		
Deputy Director for Program Policy, BHI					
Irwin Wolkstein Manuel Levine (Assistant Deputy		1-68	6-75		
Director) Melvin Blumental		7-75 1-1-76	12 - 75 3 - 78		
Alvin Diamond (Assistant Deputy Director)		3–78	7–79		

Table 7 (cont'd)

Administration		
Harold Buzzell Robert Van Hoek (Acting) Louis Helman George Lythcott	5-4-73 2-2-75 3-28-76 8-15-77	3-27-76
Director, Bureau of Quality Assurance, HSA		
Michael Goran	3-74	3-77
Administrator, Health Care Financing Administration*		
Robert A. Derzon Leonard D. Schaeffer	6-1-77 11 - 1-78	10-31-78 6-1-80
Director, Medicare Bureau, HCFA**		
Thomas M. Tierney Mildred L. Tyasowski (Acting)	3–77 5 – 78	5-78 6-79
Director, Health Standards and Quality Bureau		
Michael Goran Helen L. Smits	3-77 12 - 22-77	

^{*}Created in 1977.

 $^{^{\}star\star}$ The Medicare Bureau was terminated in June 1979.

and BHI, and their replacement by short-term staff. The "health agencies" also reveal substantial flux, contrasted only by Goran in BQA. Not revealed in the table are the tenures of Klar (1972 to 1978), Cikins (1972 to 1978), and Jos (1972 to early 1980), the few long-tenured actors. In many ways, however, certainly to the medical community, government officials appear to be playing musical chairs.

Bureaucratic reorganization recurs regularly as well. The "health agencies" were reorganized in 1973, with the Health Services and Mental Health Administration split and, among others, HSA emerged. In 1977, the HCFA was created from existing organizations elsewhere in the government. Since mid-1979, it has been engaged in internal reorganization that has yet to run its course.

Discontinuity, conflict, personnel turnover, and reorganization are dynamic characteristics of the administrative system. Change along these dimensions seems to have a life of its own, stimulating a great desire for a minimal level of stability among those responsible for program implementation.

THE ACTORS

Many of the principal actors in the implementation of the ESRD program have been indicated above. The Congressional actors responsible for Section 299I have already been identified; others appear later in the discussion. Most are associated with either the House Committee on Ways and Means or the Senate Committee on Finance. The main executive branch organizations and officials have also been mentioned. Individual physicians are named in the text. The two most prominent physician organizations are the National Kidney Foundation and the Renal Physicians Association, and their implementation roles are analyzed below.

Patients constitute one major group of actors who deserve attention here. They play a relatively passive role in the implementation

¹NKF is actually a voluntary health association, governed by lay and medical members. It is the physicians, however, who are primarily concerned with the implementation of the ESRD program.

of the program. They are not highly organized, though the National Association of Patients on Hemodialysis and Transplantation does represent a segment of the patient community. But it is useful to discuss patients as beneficiaries, in contrast to their role in implementation.

The Beneficiaries

The estimated average annual number of patients in the ESRD program is indicated in Table 1. It is worth noting that the effect of Section 299I was to create three classes of Medicare beneficiaries receiving ESRD benefits—299I ESRD beneficiaries, disabled ESRD beneficiaries, and aged ESRD beneficiaries. Moreover, each of these three classes is entitled to Medicare benefits for all medical purposes, not just renal benefits. It is useful to disentangle how the enactment of Section 299I affected each of these three classes.

Section 299I establishes Medicare entitlement for those under 65 years of age having chronic kidney failure and requiring hemodialysis or transplantation, if they meet certain other Social Security criteria. Eligibility for benefits begins after a three-month waiting period. Individuals in this first group are "deemed to be disabled" for Medicare coverage, that is, they are legally defined as disabled. Seen in a different light, the concept of disability was both legally and conceptually extended to include those suffering from chronic kidney failure.

Entitlement to ESRD benefits for the disabled results from three related policies. First, before P.L. 92-603, several Social Security insurance programs provided monthly income support to disabled individuals. Second, Section 201 of the 1972 Amendments extends Medicare health insurance coverage to those disabled under 65 years of age. Medicare eligibility, however, begins no sooner than 24 months after eligibility is established for disability income benefits. Third, since Section 299I established a particular kidney benefit for a legally defined subset of the disabled, that same benefit had to be made available to all Medicare-eligible disabled.

The third group--the aged ESRD beneficiaries--are a subset of those over 65 years of age who are eligible for Medicare benefits. When Medicare was established in 1965, the benefits available to the aged theoretically included ESRD benefits. The 1965 law, however, while not barring kidney benefits, made no explicit reference to them. And medical criteria for accepting dialysis and transplantation patients then excluded older individuals. Even today, transplant operations are seldom performed on those over 55 years of age. But the age limit for dialysis patients steadily climbed from 55 to 60 to 65 and then was removed entirely in the late 1960s. Before P.L. 92-603, therefore, very few aged were receiving renal benefits from Medicare, Medicare policy was still being defined, and knowledge that the aged were covered for kidney failure was not widely known to either physicians or patients. But when the kidney benefit was established for those under 65, as an amendment of the extension of Medicare benefits to the disabled, it meant that the renal benefit was now to be available to the aged as well.

What are the routes by which patients become eligible for ESRD benefits for each of the three beneficiary groups? Section 299I beneficiaries meet the appropriate age, medical, and Social Security criteria and fulfill the three-month waiting period. Disabled beneficiaries under 65 may begin as 299I beneficiaries, obtain disability status or income support benefits, and then be reclassified from 299I ESRD status to disabled ESRD status. Or their kidneys may fail after designation as eligible for Medicare coverage because of their disabled status. Or kidney failure may occur so near the end of the disability 24-month waiting period that it is unnecessary to invoke the 299I mechanism with its shorter waiting period. The aged, similarly, may begin as 299I or disabled beneficiaries, pass their 65th birthday, and be reclassified as aged ESRD beneficiaries. Or their kidneys may fail after they are 65, in which case they become eligible for renal benefits without reference to the 299I waiting period.

What is the practical significance of these three ESRD beneficiary classes? First, Section 299I established a particular kidney benefit that became, de facto, coterminous with the general Medicare benefit structure, so all eligible for the former were also eligible for the latter, and vice versa. Second, Section 299I, with its shorter waiting period, became a portal-of-entry for some into the disabled ESRD beneficiary class, whereupon such individuals become eligible to enroll for monthly income support benefits from Social Security. Third, though it had no direct legal bearing on the aged, Section 299I created a particular benefit for the population under 65, which necessarily was extended to the elderly. Although it is likely that the aged would have begun to claim Medicare renal benefits during the 1970s under any circumstances, it is inconceivable that they would have done so at the level indicated in the following table without the enactment of Section 299I.

The distribution of ESRD patients among these three beneficiary groups is shown in Table 8. These data show that the disabled-renal

Table 8

AVERAGE ANNUAL ENROLLMENT OF MEDICARE ESRD BENEFICIARIES,

BY BENEFICIARY GROUP, 1974-1978

	Beneficiary Group ^a				
Calendar Year	Total Enrollment	299I Patients	Disabled Renal Patients	Aged Renal Patients	
1974	19,000	13,000	5,000	1,000	
	(100)	(68)	(26)	(5)	
1975	27,000	16,000	8,000	3,000	
	(100)	(59)	(30)	(11)	
1976	35,000 ^b	18,000	10,000	6,000	
	(100)	(51)	(29)	(17)	
1977	41,000	20,000	13,000	8,000	
	(100)	(49)	(32)	(20)	
1978	47,000 (100)	21,000 (45)	17,000 (36)	9,000 (19)	

SOURCE: Office of Financial and Actuarial Analysis, Health Care Financing Administration, March 1979.

^aPercent in parentheses.

bTotal does not add because of rounding.

patients have increased from one-quarter of the ESRD patient population in 1974 to over one-third in 1978, and that the aged-renal patients now account for one-fifth of the total ESRD patients.

The distribution of benefit payments among the three beneficiary groups is shown in Table 9. A relatively stable distribution was established by 1976, with 299I beneficiaries receiving one-half the benefit payments; disabled renal patients, slightly less than one-third; and aged renal patients one-fifth.

Table 9

ANNUAL BENEFIT PAYMENTS FOR MEDICARE ESRD BENEFICIARIES,

BY BENEFICIARY GROUP, 1974-1978^a
(\$ millions)

	Beneficiary Group ^b				
Calendar Year	Total Payments	299I Patients	Disabled Renal Patients	Aged Renal Patients	
1974	283	170	79	34	
	(100)	(60)	(28)	(12)	
1975	450	248	127	75	
	(100)	(55)	(28)	(17)	
1976	598	309	172	117	
	(100)	(52)	(29)	(20)	
1977	757	381	223	153	
	(100)	(50)	(29)	(20)	
1978	947	464	284	199	
	(100)	(49)	(30)	(21)	

SOURCE: Office of Financial and Actuarial Analysis, Health Care Financing Administration, March 1979.

Some have argued, on the basis of these data, that the cost of the program authorized by Section 299I should be narrowly restricted to those figures in the 299I column. The costs attributable to the disabled and aged ESRD beneficiaries, they assert, would have been

^aIncurred basis.

Percent in parentheses.

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incurred in any event because the general Medicare benefit includes the special kidney benefit. This is a misleading argument. It conveniently ignores the effect Section 299I had on establishing a Medicare-wide policy toward end-stage renal disease and disregards the dynamic interaction between the benefit categories.

The ESRD beneficiary population is also distributed between those entitled to benefits because they receive dialysis and those entitled by reason of kidney transplant. Table 10 shows the distribution by reason of entitlement. The data are not entirely satisfactory, partly because of the interactions between the two treatments and partly because of the problems of counting. On the one hand, many prospective transplant recipients are on dialysis while awaiting a kidney; so a third column—"on dialysis awaiting a transplant"—would be more revealing than the two-column table. Furthermore, the transplant column includes only those ESRD beneficiaries who have had successful kidney transplants and are currently entitled to Medicare benefits. From 1971 through 1978, the entitlement period was limited to 12 months after the month of the operation; thereafter, patients ceased to be enrolled beneficiaries.

Table 10

AVERAGE ANNUAL ENROLLMENT OF MEDICARE ESRD BENEFICIARIES,
BY REASON OF ENTITLEMENT, 1974-1978

Calendar Year	Total Enrollment	Transplant Patients on Rolls	Dialysis Patients on Rolls
1974	19,000	2,000	17,000
1975	27,000	2,000	25,000
1976	35,000	3,000	32,000
1977	41,000	2,000	39,000
1978	47,000	2,000	45,000

SOURCE: Office of Financial and Actuarial Analysis, Health Care Financing Administration, March 1979.

¹This entitlement period was lengthened to 36 months by Public Law 95-292, June 13, 1978.

Notwithstanding these difficulties, Table 11 is instructive relative to program benefit payments between the two treatments. The data indicate that while benefit payments for transplantation in 1978 were two-thirds higher than in 1974, such payments had declined from 18 percent to 9 percent of the total program in that period. Increasingly, the ESRD program is a dialysis program.

Table 11

ANNUAL BENEFIT PAYMENTS FOR MEDICARE ESRD BENEFICIARIES,

BY REASON OF ENTITLEMENT, 1974-1978^a

(\$ millions)

Calendar Year	Total Payments	Transplant ^C	Dialysis
1974	\$283	\$51	\$232
	(100)	(18)	(82)
1975	450	74	376
	(100)	(16)	(84)
1976	598	75	523
	(100)	(13)	(87)
1977	757	72	685
	(100)	(10)	(90)
1978	947	87	860
	(100)	(9)	(91)

SOURCE: Office of Financial and Actuarial Analysis, Health Care Financing Administration, March 1979.

We have presented an overview of the ESRD program in this section. In subsequent sections we analyze the implementation of the program with emphasis on planning.

^aIncurred basis.

Percent in parentheses.

^cIncludes surgical costs and costs of post-operative care through the 12-month entitlement period.

IV. THE ESRD INTERIM PROGRAM: INITIAL PLANNING

Section 299I became effective on July 1, 1973, thus limiting the time for planning for the ESRD program to the eight preceding months dating from enactment of P.L. 92-603. In this section, we describe the initial education of the government to the task of implementing the new program, analyze the development of the interim regulations, and examine the content of those regulations.

EDUCATION

When the Bureau of Health Insurance (BHI) set out to write and publish regulations implementing Section 2991, its experience with endstage renal disease was extremely limited. There were few elderly dialysis patients, for example, because prevailing medical opinion generally regarded them as unsuitable for dialysis or transplantation. BHI had received several inquiries in 1971 about reimbursement of dialysis for Medicare beneficiaries, and had reached several decisions by spring of the following year. First, hospital-based hemodialysis was covered as "services of physician-directed clinics," including costs of equipment and necessary services and supplies. Second, dialysis outside the hospital was covered under "the prosthetic device provisions of Sec. 1861 (s)(8)," for costs of necessary equipment, services, and supplies. Finally, routine physician services were included in a single charge for treatment, while nonroutine, periodic, or emergency services for a particular patient was separately billed. A charge of \$10 for physician services was considered "reasonable"; a \$50 charge, excessive. But these decisions were contained in some correspondence and a few memoranda; they represented only the rudiments of a Medicare policy.

BHI responded to the need to educate itself about end-stage renal disease by convening a work group on the subject. The members included Philip Jos, chairman, Division of Systems, BHI; Milton Cikins, Office

Public Health Service data for early 1971 indicated that, of approximately 3,500 persons then on dialysis in the U.S., there were only 104 patients in the 60-64 age group, and only 40 patients over 65.

of Program Policy, BHI; Marian Fiasca, Division of State Operations, BHI; Joseph Ciaravella, Division of Contractor Operations, BHI; and Mendel Kaufman, Division of Health Insurance, Office of Research and Statistics, SSA. Each member brought a different organizational perspective to the implementation task: "Systems" was involved with computer programming, data generation from facilities, and administrative problems of beneficiary procedures and claims processing, and Jos had previously acted as liaison between systems and policy. "Policy" dealt with provider and medical services policy, provider reimbursement, and conformance of new policy with existing statutes and regulations; Cikins was from the branch dealing mainly with coverage of physician services. "State Operations" dealt with the health and safety regulations governing Medicare-participating institutions; Fiasca's background was in utilization review and had brought her into extensive prior contact with PHS personnel. "Contractor Operations" dealt with processing of Medicare claims by fiscal intermediaries and carriers, while "Research and Statistics" of SSA had general data processing and analysis responsibilities.

The work group met with other government agencies—the National Institutes of Health, RMPS—and representatives of the medical community during November and December of 1972. A number of problems were identified, all of which pointed to the data, which were skimpy or nonexistent, poor in quality, and often displayed great variation without clear patterns. There were great differences in charges for dialysis and transplant services; charges did not always bear much relationship to costs; and detailed questions that required good data to answer were simply beyond evaluation. The bases and amount of physician reimbursement appropriate for dialysis was difficult to determine because charges varied widely across the nation and substantial differences existed in views about how much direct physician supervision was required for dialysis patients. Basic information on the number, identity, and existing capacity of dialysis facilities was not readily available.

Although the work group educated its members, it did not function as a group and individuals responded more to their parent organizations. Wolkstein and Smith assumed policy leadership, dealt with the medical community, and relied upon Cikins for staff work; Jos also maintained

contact with the medical community and worried about operational problems; Fiasca began to draft "health and safety" regulations.

Between November and February, the Kidney Disease Control Program of RMPS supplied BHI with many documents, reports, guidelines, and papers, a list of dialysis and transplant facilities, and cost data on cadaver organ procurement and home dialysis training. Later, the organization provided detailed comments on draft regulations.

The National Kidney Foundation (NKF), which had participated in the legislation, immediately offered its assistance to the BHI. It sought to establish itself as the dominant spokesman for the nephrology community, but was unable to prevent individual physicians from dealing directly with BHI personnel. In the early months of planning, however, the NKF played an important educational role.

During these early months, H splashed into prominence on the front page of the New York Times. Klar, after passage of P.L. 92-603, noted that the cost estimates used by Senator Hartke showed no growth as successive patient cohorts were added to the beneficiary population base. He prepared a life table on end-stage renal disease patients and made his own estimates. Where Hartke had estimated \$125 million first year costs to Medicare and \$250 million in the fourth year, Klar estimated total national costs of \$158 million in the first year, nearly \$600 million for the fifth year, and \$1 billion in the 10th year. These calculations were conveyed first to Assistant Secretary for Health DuVal and then by him to Secretary Elliott Richardson. Indicative of the strained relationships between the department and SSA/BHI, was the subsequent decision by the H public affairs officer to leak the numbers to the New York Times rather than send them over to SSA for comment. The ensuing controversy involved the Times' editorial board, the National Kidney Foundation, members and staff of the Senate Finance Committee, the SSA Actuary, and officials in H. Though Klar's estimates were

¹Klar's estimates were based on 1972 dollars.

²See: R. D. Lyons, "Program to Aid Kidney Victims Faces Millions in Excess Costs," New York Times, January 11, 1973, p. 1; "Medicarelessness," editorial, New York Times, January 14, 1973; L. K. Altman, "Kidney Foundation Criticizes Articles on Care Costs," New York Times, January 18, 1973; and L. K. Altman, "Costs of Kidney Therapy: Two Fundamental Questions Raised," New York Times, January 23, 1973.

clearly better than those used by the Congress in October, their presentation in the national press did little to facilitate good relations with SSA.

The landmark educational event was a BHI-sponsored conference with a number of physicians, held in Baltimore on February 8 and 9, 1973, called to define the issues for the ESRD program. The letter of invitation stated:

Policies and processes have to be developed and integrated into the existing systems for determining the individual's entitlement, defining covered services, and making appropriate payment—and, in accordance with the provision of the law for applying standards of minimal acceptable utilization, establishing such standards and determining which institutions meet them.

Two committees—transplantation and dialysis—addressed coverage, reimbursement, and conditions of participation. The transplant committee agreed that the minimum annual transplant rate for a given facility should be 26 in the first year and 50 in the second, and that all applications for new centers should receive careful scrutiny. The dialysis committee discussed a number of detailed issues—when a "course of dialysis" begins, the frequency of dialysis in hours per week, the need for treating dialysis facilities as separate cost centers, and the distribution of home dialysis supplies to patients by sponsoring organizations. Discussion favored reimbursement for physician services on a monthly retainer basis and a flat fee for home training.

BHI officials at this meeting sought to understand the treatment of end-stage renal disease in terms of Medicare policies and procedures. They wanted to be sure that a benefit payment process was installed in time and thus keep their obligation to patients. The physicians, on the other hand, were seeking to persuade the government of the need for

The conference participants included 14 physicians and surgeons from outside the government, most having strong ties to the National Kidney Foundation and principal affiliations with academic medicine. Notables included: E. Lovell Becker, president, and George E. Schreiner, past president, NKF; Belding H. Scribner, University of Washington; Constantine L. Hampers, then president of National Medical Care, Inc., but identified only as director of dialysis, Peter Bent Brigham Hospital,

a program organizing services into six to eight regional networks, each having a stratified hierarchy of treatment facilities, with medical review conducted at national, regional, and local levels. This was a concern beyond the jurisdiction of BHI. The H representatives did not participate in the conference discussion, but afterward concluded that a role for H existed in the ESRD program, especially on medical issues and the organization of the medical care system.

DEVELOPING THE INTERIM REGULATIONS

The implementation problem structure for the ESRD program derived from the statute, the major administrative tasks of Medicare, and the views of the medical community and consisted of the following elements:

- o Patient eligibility and entitlement,
- o Facility qualification or certification,
- o Facility reimbursement,
- o Physician reimbursement,
- o Minimum utilization rates for covered procedures,
- o Medical review boards,
- o Claims processing, and
- o The medical information system.

Because patient eligibility and entitlement were prescribed quite thoroughly by the statute, regulation development focused on the remaining elements.

Underlying this implementation issue structure were three closely related policy issues--participation, coverage, and reimbursement--about which policy planning decisions had to be made.

Boston; and transplant surgeons Samuel Kountz, Downstate Medical Center, George M. Williams, Johns Hopkins, and David Hume, Medical College of Virginia. Representatives of the American Association of Nephrology Nurses and Technicians and of the National Association for Patients on Hemodialysis and Transplantation were present, as were consultants from the NIH, RMPS, Vocational Rehabilitation Administration, Veterans Administration, and elsewhere. Klar and Scott Fleming, his superior, represented H, though they had not been invited.

Technically speaking, participation refers to the status of certified hospitals, skilled nursing facilities, and home health agencies. These "provider" institutions must meet certain "conditions of participation"--specified health and safety standards--to be certified for reimbursement from the Hospital Insurance Trust Fund (Part A) for services provided Medicare beneficiaries. Nonprovider and "supplier" institutions, that offer, for example, independent laboratory services or portable x-ray services, must meet "conditions of coverage" to be reimbursed by the Supplementary Medical Insurance Trust Fund (Part B). Nonhospital, limited care dialysis facilities were nonprovider institutions, and thus were in the same category as suppliers. The generic issue for the ESRD program was which institutions, provider and nonprovider, would be certified to be reimbursed for treating patients. Minimum utilization rates and medical review boards were subsumed as conditions of either participation or coverage, depending on whether the institution was a provider or nonprovider.

Coverage refers to the conditions to be met by nonprovider institutions to be certified for reimbursement purposes, that is, the "conditions of coverage" required of nonhospital, limited care dialysis facilities. Coverage also refers to the specified service to be reimbursed; tissue typing of recipients and potential kidney donors done in connection with transplantation is a covered service of a provider institution. The generic purpose of coverage decisions, therefore, is to specify the bases for reimbursement.

Reimbursement means financial compensation for covered services provided by certified institutions. Important considerations include the bases of reimbursement (that is, provider institutions are reimbursed on a cost basis, while nonproviders are reimbursed on a charge basis), and administrative mechanisms of payment (retrospective versus prospective reimbursement). BHI faced issues of facility reimbursement and physician reimbursement in developing implementing regulations for the ESRD program.

Conditions of Participation and Coverage

The work group member from the Division of State Operations (DSO), Marian Fiasca, quickly produced a draft of regulations on participation by early December 1972. Because DSO was part of the Office of Program Operations, it reported directly to the BHI director and not through the Office of Program Policy. So the early draft regulations were prepared before Wolkstein asserted control over regulation development.

The initial draft was dated December 8 and 19, 1972. With minor modifications, this served as a framework for a more extensive February 1973 draft, which was widely circulated within BHI, SSA, and elsewhere in HEW, and was also transmitted to the medical community. A subsequent revision carried an April 25, 1973, date. Finally, a May 14, 1973, draft was prepared, the last prior to the Interim Regulations. These drafts, comments on them, and their successive changes reveal the controversy in the participation issue.

The February draft addressed the statutory requirements of minimum utilization rates for covered services and medical review boards "to screen the appropriateness of patients for the proposed treatment procedures." To do this, the draft created a typology of institutions. There were hospital-based Kidney Disease Treatment Centers (KDTCs) of two types: a Kidney Disease Transplant and Dialysis Center (KDTDC) and a Renal Dialysis Center (RDC). There were also Satellite Dialysis Units, out-of-hospital entities affiliated with either a KDTDC or RDC; and Community Hemodialysis Units, free-standing, limited care nonhospital institutions. Basic elements of the thinking of the KDCP and NKF were evident in the hierarchy of the "tertiary" major medical center at which the transplant and dialysis center was to be located, and the "secondary" community hospital dialysis center. Also, the affiliation required of each institution gave prominence to the transplant center as the focal point of the delivery system.

Minimum utilization rates were stipulated for each of these institutions. The KDTDC was to serve exclusively a population base of 2 million and to have a capability of performing 50 transplants each year, with 26 transplants per year to be the minimum rate at the end of the first year; the optimum level was indicated to be 100 operations per year. It was also to provide acute dialysis services, and to calculate its maintenance dialysis workload on the basis of 2-1/2 patients per

station per week, and a population base of at least 500,000. The limited care facility was to calculate its workload on the basis of 2-1/2 patients per station, and was to have two shifts per day, five days per week.

Medical review boards were proposed for each facility "to screen the appropriateness of the proposed treatment procedures for accepted patients," that is, to determine the suitability of transplantation and home dialysis for particular patients. Composition, procedures, and responsibilities of review boards were set forth, and relationships among review bodies of the different types of facilities were indicated.

Comments on the draft regulations raised questions about minimum utilization rates: How was utilization to be defined and measured? How were inconsistencies in proposed requirements for different facility types justified? What was the rationale for permitting exceptions to the requirements? Medical review boards also elicited questions: Was the scope of responsibilities too great? Was a separate renal committee necessary where hospitals had a quality assurance program? It was also noted that there were no differences in services, except for proprietorship, between satellite dialysis units and limited care facilities. Clearly, no consensus existed within BHI, SSA, or HEW. Revision was called for.

Wolkstein, in a statement of his personal views circulated on April 10, attacked the assumptions underlying the thinking of the National Kidney Foundation and the KDCP which were reflected in the Division of State Operations draft regulations. A general agreement existed, he wrote, that transplantation should be done only in "tertiary" centers, but dialysis posed several problems when analyzed in terms of the tertiary-secondary-primary hierarchy. First, it was unclear whether "primary care" had any meaning. More importantly, the hierarchy was based on the site of care, not on the level of care to the patient. "Many patients treated at higher level sites," he wrote, "are identical to

 $^{^{1}\}mathrm{This}$ formulation reversed the language of Section 299I, which called for review "to screen the appropriateness of patients for the proposed treatment procedures."

²Route Slip, from Irwin Wolkstein, to Robert Mayne, Morris Levy, April 10, 1973, transmitting "Application to Medicare Coverage of Renal Disease of Theory of Medical Care Organization into Tertiary, Secondary, and Primary Care Sites," April 10, 1973.

those treated at the lower levels because the so-called higher level sites perform community care and do not reject the less complex cases." An important consequence of this fact was that hospitals provided lower levels of care at costs "substantially above" nonhospital facilities. This posed a sharp challenge to DSO, which was oriented to hospital-based services, a challenge reiterated in a nine-page paper distributed by the Office of Program Policy two weeks later. 1

A revised "Conditions of Participation" was circulated by D30 in late April. The new draft eliminated the typology of facilities and referred only to hospitals that provided "kidney dialysis and/or kidney transplant services." The most significant addition was the requirement that such hospitals "must coordinate" their efforts with other facilities through "network agreements among all kidney treatment facilities within designated geographic areas [emphasis added]." The major purpose of these agreements was "to establish a system for the exchange of patients and medical information," a purpose to be accomplished by creating medical review boards at the network level, not at individual institutions. The review boards were to evaluate proposed patient treatment plans, review them twice a year, and assure that each patient was receiving appropriate medical care. A number of other changes from the February draft were proposed.

Views on this draft were opposite from those on the February document. Where the KDCP had found the early draft to their liking, they complained that an entire rewriting of this version was needed to bring it "to a professionally and administratively acceptable level." In BHI, on the other hand, Wolkstein found it "a tremendous improvement." The comments generated further questions on minimum utilization rates, however, and revealed the continued absence of consensus within BHI, let alone HEW.

¹Office of Program Policy, "Statement of Issues for the Implementation of Section 299I of P.L. 92-603," April 24, 1973.

²Division of State Operations, BHI, "Conditions of Participation," April 25, 1973.

³An early April revision of "Conditions of Coverage" for nonhospital dialysis facilities also included a requirement for network affiliations.

While these events were occurring, Klar was becoming actively involved in the regulation development process. In February and March, he sought to identify the national issues in the ESRD program, communicating with physicians across the country and querying the KDCP group within RMPS on their views. In April and May, he generated a series of outlines focusing on medical and clinical issues in the ESRD program. An April 16 outline addressed the issues of home versus limited care dialysis and the choice of therapy within a regional or "network" pattern of organization. One, dated May 9, 1973, outlined a "Kidney Disease Treatment Network," coordinated by a new entity--a Kidney Treatment Center; the outline emphasized the distribution of organizational responsibilities and functions in a stratified system of institutional relationships. A "quality control" section outlined responsibilities for a "National Renal Disease Advisory Council," regional renal disease advisory councils, medical review boards, state health agencies, HEW, SSA intermediaries, and BHI.

DSO now found itself in a quandary. Initially it had been attentive to the views of the RMPS kidney staff. More recently, it had begun to pay closer attention to the internal BHI comments on its draft regulations. Now, in response to Klar's forceful, if somewhat unclear, intervention, it prepared "Draft of Regulations No. 5 -- Subpart R: Conditions for Coverage of Services of Kidney Treatment Centers," on May 14, 1973, but complained in its cover memorandum that "The current draft differs considerably from the old one because of the suggestion, by Dr. Ronald Klar of the Office of the Under Secretary [sic] for Health, that we adopt the concept of a 'Kidney Treatment Center.'" This new entity was to oversee the implementation of the network agreement-- "planning, arranging, monitoring, and coordinating programs of treatment

Dr. Edward M. Hinman responded, for example, to a request from Klar with a six-page memorandum setting forth his view of "the key issues needing resolution at this time." These included the development and implementation of a national plan, development of a data system, allowance for technical advance in treatment, and the relationship of the VA's renal program to the Medicare program. See the Memorandum from the Director, DPTD, RMPS, to the Deputy Assistant Secretary for Health Policy Development, "Implementation of Section 299I, P.L. 92-603," March 23, 1973.

for individuals"--but would not have any direct responsibility for providing either transplant or dialysis services.

DSO assumed from the beginning that one set of ESRD regulations would be needed for hospital transplant and dialysis services and another for nonhospital dialysis facilities, an institutional approach. Although it was obvious that the proposed "Kidney Treatment Center" required special regulations, DSO was unclear about how to proceed. It preferred to go forward as planned. But Klar suggested one set of regulations for transplantation and another for dialysis, a treatment approach, thus inverting the DSO preference and creating much confusion. In mid-May, only a month and a half remained before the program became operational, but no consensus had emerged within the bureaucracy on the issue of participation. The July 1 deadline and the obvious complexity of the participation issues reinforced other pressures favoring a simple "interim" response. 1

Reimbursement

Within BHI, reimbursement was the clear responsibility of the Office of Program Policy, which discussed the main issues in a late March paper. The kidney amendment, it was argued, required a total review of Medicare coverage policies for transplantation and dialysis because of their enormous cost potential and the virtual disappearance of a non-Medicare population as a base of comparison for Medicare's cost and charge determinations. The paper dealt with the coverage issues of (1) physician's services reimbursement, (2) transplant services, (3) the level of "reasonable and necessary" care, (4) home dialysis aides, and (5) laboratory tests. Physician reimbursement confronted Medicare with problems of wide variation in reimbursement

The Office of Program Policy, in "Statement of Issues for Implementation of Section 299I of P.L. 92-603," 4/24/73, p. 4, suggested an "interim" solution to participation: "It may be that one way to ease the way into the program would be to qualify all existing facilities for patients now being treated therein until there can be a reasonable transfer of such patients to a permanently qualified facility or to home dialysis or transplant."

²Office of Program Policy, "Chronic Renal Disease Provisions of P.L. 92-603: Basic Coverage Policy Considerations," March 30, 1973.

rates; a California study, for example, showed physician charges ranging from \$5.68 to \$111.49 per dialysis session! Other problems included variation in treating stabilized patients, dealing with medical complications, and conducting periodic full examinations.

The determination of the appropriate level of care concerned both treatment site and means of treatment, and was necessary to assure that patients were considered "for all medically feasible alternatives." Given increasing dialysis costs as one moved from home to limited care to hospital settings, the paper argued, "it is important to assure that patients receive care at the lowest-cost necessary level." But judgments about appropriateness of care were medical decisions, however limited by socioeconomic and demographic factors, and would be made at the "point of medical care" and also by the fiscal intermediary level.

Mechanisms were considered to require facilities to encourage the lowest-cost care of transplantation and home dialysis. Evidence of compliance could be the proportion of patients trained for selfdialysis, and the incentive mentioned was a draconian financial one:

To enforce the provision, there could be a reduction in payment to the facility, e.g., when competent medical opinion prescribes home dialysis treatments for a patient and training facilities for home dialysis are available, but the patient chooses facility services for reasons of convenience, after a suitable time interval the program liability could be limited to something like the prevailing charge (or cost) for home dialysis service and the excess cost would be considered noncovered and an obligation of the patient.

The acknowledged problem with such a requirement was its dependence on incentives to both patients and facilities, incentives that were almost exclusively financial—a constraint on free expression of patient choice and a dependence ultimately on "competent medical opinion." This analysis reflected a fairly sophisticated appreciation of the policy issues rather early in the policy planning stage.

l_{Ibid}.

In early April, Wolkstein circulated a paper on the reimbursement issues confronting BHI, which suggested various approaches without favoring any. The themes running through the paper included the effect of the near-universal renal benefit in eliminating the private market as a standard-setting base; the need to impose limits on reimbursable services; and the absence of adequate data for doing so. Issues of facility dialysis reimbursement considered were the requirement of separate cost centers for hospital dialysis and home training, reimbursement on an hourly basis, limiting reimbursement to estimated costs, and limiting the quantity and type of laboratory services. Home dialysis reimbursement possibilities included relying upon sponsoring institutions to manage equipment and supplies for home patients, limiting allowable costs to an annual allowance, and for patients having contracts with suppliers prior to July 1, 1973, providing a transition to a later time when sponsoring institutions might manage such arrangements. 2

The possible approaches to physician reimbursement for dialysis included the use of hourly rates, customary fees, relative value scales, or a retainer (a capitation approach). The latter received the most attention, with the notion advanced that different retainer levels would be required for home and center dialysis and, further, that a sliding scale might be employed as the number of patients under supervision of one physician reached some (unspecified) numerical level. The need was recognized for the reimbursement of post-surgery follow-up care to transplant patients. The paper, though it reached no conclusions, was designed to elicit comment about a wide range of possible reimbursement arrangements.

One very important response to Wolkstein's "issues" paper came from Arthur Hess, acting commissioner of the Social Security Administration, and was directed to Thomas Tierney, director of BHI. Hess suggested

¹Office of Program Policy, "Statement of Issues, Alternatives, and Background on Reimbursement Policy for Hemodialysis, Kidney Transplants, and Physician Services Under Section 299I of P.L. 92-603," April 1973.

²This particular problem prompted the suggestion that "There appears to be a need for an interim policy and a permanent policy for reimbursement for home dialysis," thus contributing to growing pressure for an interim program.

that reimbursement procedures for renal disease stay close to existing procedures now and be changed later if warranted by experience. Wolkstein, greatly concerned, wrote Tierney:

. . . I believe our policy problems are more serious than Art's note suggests. We have already done a lot of the data gathering and studying that Art mentions for the future and have reached the conclusion that rules that suggest we stay pretty close to the present reimbursement methods are not going to be appropriate, or acceptable, to start the new program with. If we wait until after post-July 1 experience is gained to change the present rules, the cost of the dialysis and transplant program may be as much as 2 or 3 times the previously estimated cost.

He noted that some physician advisers were advocating "a much tighter approach" than existing practice, and also that program cost would obviously be of concern to HEW and the Office of Management and Budget. The problems with existing reimbursement procedures were the relative newness of dialysis, the lack of sufficient time or incentive for private health insurance organizations to determine appropriate payment for services provided, and the "very easy-going" attitudes toward cost of such organizations because of the few dollars at stake. Programs having wide coverage, Wolkstein wrote, and substantial government funds, were generally much tighter.

Physician reimbursement highlighted the problems. Some private insurers were paying physicians exorbitant rates, thus providing no help to Medicare. On the other hand, a large number of experts believed that there should be "virtually no personal physician, medical component for routine chronic hemodialysis." Summarizing the dilemma, Wolkstein wrote:

So at one end we are faced with the knowledge that present payment methods by insurance programs, including Medicare, are virtually uncontrolled, inconsistent and irrational, and at the other end we are faced with the belief that ongoing routine dialysis warrants virtually no physicians' services for which payment should be made on a fee-for-service basis.

Without policies that were well thought out on this and other issues, he feared that the costs of dialysis would be "extremely disproportionate to the value of the services."

These policy issues were sufficiently complex and sensitive, however, that the "issues paper" had highly tentative language. "If we tried to surface our real views now," Wolkstein wrote, it would have required a long time to secure clearances within HEW and "we would be . . . prematurely taking on a heated controversy from those who have something to gain from very liberal rules of payment." It was hoped that the issues paper would draw considerable reaction and comment, without committing the Secretary to any position, and that SSA could then send a proposed policy document to the Secretary in early May.

An April 23, 1973, paper, however, indicated that BHI still had some distance to go to resolve the outstanding policy issues. Still being considered as an incentive for dialysis facilities to encourage home dialysis was reducing facility payment when "competent medical opinions" prescribed home treatment, home training was available, but the patient chose institutional care. Facility reimbursement possibilities being considered included limits based on estimated cost; and reimbursement on a per treatment basis, hourly rates, or a combination of both. The physician reimbursement discussion noted the limited applicability of fee-for-service, the infeasibility of hourly rates, and the "innovative" nature of a retainer, suggesting resolution was near on this issue.

In this context, Klar in H, began to address issues of reimbursement, through a series of brief outlines dated, respectively, April 16, April 30, and May 19. The one dated April 30 discussed, among other things, cost containment. It suggested limiting the number of facilities and covered services, and encouraging less costly forms of treatment. Eliminating the co-insurance provision for home dialysis and the threemonth waiting period for transplantation were suggested. These ideas were only sketchily developed, however, did not address the limits imposed by the statute, and often reflected a distillation of thinking going on elsewhere within the department.

¹Office of Policy Program Policy, "Statement of Issues for the Implementation of Section 299I of Public Law 92-603," April 23, 1973.

Several meetings in April and May helped to focus the implementation issues. One on April 18 involved Congressional staff and HEW representatives. The Congressional staff saw the renal program as a "showcase amendment" and a potential precedent for either catastrophic or national health insurance. They emphasized the unprecedented authority provided to the Secretary to establish new methods of quality and cost control, and urged that the strategy of implementation be stringent and cautious initially. Specifically, the staff recommended strictly limiting the number of transplant centers, incorporating strong pressures for self-dialysis in the conditions for participation, avoiding feefor-service in reimbursing dialysis physicians, establishing an ad hoc national advisory group to set criteria for conditions of participation and determine appropriate levels of care, and setting up a national kidney registry to stimulate transplantation.

An important meeting, wholly internal to HEW, was held May 7, 1973, to consider reimbursement methods. ² It was recognized that "innovative approaches" could not be fully implemented by July 1, and consequently that both interim and long-range techniques needed to be developed. Even so, far-reaching changes would be required for physician reimbursement: direct patient care in routine dialysis would not be reimbursed; reimbursement for the stable patient would be limited to one office visit per month and a single in-depth examination semi-annually; nonroutine services would be reimbursed on a fee-for-service basis where "reasonable and necessary" and supported by documentation; and the general supervision of a facility would be included in the facility's overhead charge. The retainer or capitation concept was shelved for the moment. Regarding facility reimbursement, the only conclusion reached was that, during the interim period, the "present reimbursement level would be

The departmental representatives included Henry Simmons, Eugene Rubel, Scott Fleming, Ronald Klar, Ian Mitchell, John Zapp, William Bauer, and William Sobaski. BHI was represented by Irwin Wolkstein, Robert Smith, and Phil Jos. Bill Fullerton was present from the House Ways and Means staff, as were Senate finance staff Jay Constantine and James Mongan.

²Klar, Fleming, Harriman, and Levisohn represented H; Wolkstein, Smith, Vandergrift, Jos, Cikins, and Dickinson represented BHI.

maintained." Much discussion focused on how the government ought to set the price for reimbursing dialysis treatment, whether by a uniform price or ceiling applied to all facilities, whether hospital or free-standing, or by a government invitation to facilities to submit "bids" for providing a given level of services. Both approaches were to be explored further. The impact of economic incentives to facilities on the quality of care provided was also recognized as a problem. The only other issue resolved was that the ESRD program would make no payment to donors of organs for transplantation; the government would not create a market in vital organs! Though some issues remained unresolved, movement was occurring on the reimbursement issues.

The Medical Community

In late 1972 and early 1973, the National Kidney Foundation spear-headed medical community efforts to influence the development of the implementing regulations. It supplied information about dialysis and transplantation to a receptive BHI and helped organize the Baltimore meeting in February 1973. Later, it assembled a group of physicians that drafted a "White Paper" in spring 1973. The "overriding principle" of the White Paper held that all concerned must "design a program which assures access to medical care at reasonable costs for the patient" and satisfies patients that the care is "of optimal quality."

The White Paper noted that the preferred institutional system of care had been described in 1972. It further suggested that the primary patient selection criterion be those patients with end-stage renal disease "otherwise anticipated to have a reasonable chance for long-term survival and rehabilitation [emphasis added]." This implied a preference for a severe selection criterion, without acknowledging the factors that would make the use of such a criterion highly unlikely. These factors included the absence of acceptable health status indicators that

¹National Kidney Foundation, "Guidelines for the Implementation of Public Law 92-603, Title II, Section 299I, Concerned with Chronic Renal Disease," April 1973. This report was issued in final form in August 1973.

²National Kidney Foundation, "The Optimal Facilities Necessary for Diagnosis and Management of Patients with End-Stage Renal Disease," prepared for the Regional Medical Programs Service, June 13, 1972.

would permit discrimination among potential patients on rehabilitation grounds, the steady relaxation of selection criteria that had occurred in the years before Section 299I, and the effect of Section 299I on physician decisionmaking in removing scarcity as a selection criterion. Rather than an outcome-oriented criterion, the NKF opted for a process criterion—evaluation of patients by physicians and consultation among physicians about appropriate treatment.

The paper made several recommendations for reimbursement of facilities: in-patient, hospital-based dialysis should be on a cost basis; limited care dialysis charges should be limited to a range of \$120 to \$150 per treatment, "exclusive of physicians fees, special laboratory procedures, and in-patient care for complications and intercurrent illnesses"; satellite dialysis at an out-patient hospital might be reimbursed at 1.3 times the average regional prevailing rate for limited care dialysis. Home dialysis reimbursement should include stabilization, not to exceed eight weeks, home training at the limited care rate plus a nonrecurring flat fee per patient of \$1,000 to \$1,200, home training centers to be accountable for equipment and supplies, and chronic maintenance dialysis limited to \$5,000 to \$11,000 per patient annually. It was also suggested that compensation for the home dialysis patient, helper, or both be considered, as well as the reuse of disposable dialyzers.

Physician reimbursement for in-patient treatment was to be the existing reasonable and customary Medicare procedure. Limited care, regardless of payment method, should not exceed \$250 per month per patient. Home training should carry an \$800 flat fee, in addition to the limited care maintenance fee. Home dialysis maintenance, it was suggested, "may be equal to that of limited care for the first year . . . but will decrease to 50 percent of the established level for all subsequent years."

The NKF report, which also dealt with medical review boards and minimum utilization rates, revealed two deeply ingrained assumptions of the medical community about how federal health programs should be implemented. First, it recommended that formal advisory committees of physicians be created at all levels—national, regional, and local—to guide the government. Second, the report evolved from a process

designed to generate consensus within the medical community, consensus that implicitly was deemed to be an expression of the public interest.

THE INTERIM REGULATIONS

The several strands of activity of early 1973 came together in May and June, resulting specifically in the publication of interim regulations and generally in an internal HEW identification of the issues of a long-term program.

Recommendations came from numerous persons to establish an interim ESRD program in the interests of going operational on the required date. Once the staff at the lower bureaucratic levels agreed that an interim response was essential for reimbursement issues, the energies of BHI and SSA turned to drafting, clearing, and publishing interim regulations. The writing took place in late May and early June; a completed package went to the SSA commissioner by mid-June, was signed by him on June 22; Secretary Weinberger signed off on June 26; and interim regulations were published in the Federal Register on June 29, 1973.

Prior to publication, however, there was much discussion at the Secretarial level both about the interim program and the main dimensions of the long-term program. The basic document was a memorandum from Assistant Secretary Edwards to Secretary Weinberger, prepared by Klar, dated June 7, 1973, which addressed both interim and long-term program issues. The interim program discussion reiterated positions already agreed to by SSA/BHI and H. On June 11, the Under Secretary of HEW signed off on the interim period policy recommendations in the Edwards memorandum. And the Acting Commissioner of Social Security, in transmitting the final regulations to the Secretary, referred to the June 7 document as the basis for interim program policy decisions.

¹38 Federal Register 17210, June 29, 1973.

Memorandum, from Assistant Secretary for Health, to the Secretary, "Kidney Disease Benefits under Medicare-Policy Issues: Summary," June 7, 1973.

Memorandum, from Assistant Executive Secretary for Health, to Dr. Charles Edwards, Assistant Secretary for Health, "Kidney Disease Benefits under Medicare--Your Memo of June 7," June 11, 1973.

Memorandum, from Acting Commissioner of Social Security, to the Secretary, "Amendments to Subparts A, B, D, and E of Regulations No. 5

The proposed long-term program had three major elements. First, a "network" was recommended consisting of kidney disease treatment centers, transplant units, and maintenance dialysis units. Networks would serve minimum population bases and help contain costs by insuring facility utilization, while also helping to maintain quality of care. Kidney disease treatment centers would manage the medical review function, selecting patients, reviewing treatment modality and setting, and monitoring patient care. Transplant centers, limited to 100, would be affiliated with perhaps four such centers. Maintenance dialysis would be encouraged in limited care, self-care, and home settings. Second, it was recommended that all maintenance dialysis, in hospital and non-hospital units, be based on reasonable charges. Finally, a "national renal disease review board" was proposed to provide for participation in the program by outside professionals. The Edwards memorandum to Secretary Weinberger proposed also that there be a joint press conference at which the Assistant Secretary for Health and the Commissioner of Social Security describe the essential features of both the interim and longterm programs.

The proposal drew little support and some critical opposition.

BHI objected to the proposed reimbursement approach; they were far from persuaded of the wisdom of moving all maintenance dialysis out of hospitals. But it was the Office of the Assistant Secretary for Planning and Evaluation (ASPE) in the Office of the Secretary that proved to be the key source of opposition. In a mid-June meeting with the Secretary and Under Secretary, Stuart Altman attacked the network concept on grounds that it would establish "franchises" to provide treatment for renal disease and, given the complexity of the proposed arrangements, persuaded the Secretary to defer any announcement about the long-term program.

So, on June 29, 1973, interim regulations were published to guide the ESRD program. The preamble set forth the basic justification for the interim program:

Setting Forth Interim Policies and Procedures for Payment for Services in Connection with Kidney Transplant and Renal Dialysis Provided to Entitled Beneficiaries—Action," June 22, 1973.

In the view of the new issues that stem from the virtually universal coverage of a very complex service, the absence of prior experience, and possible precedents that the regulations may establish, final decisions on Medicare payment and facility qualification policies will require careful study and reevaluation based upon operating experience. Operations on July 1, 1973, are to be based upon interim regulations.

These regulations did not provide for minimum utilization rates and medical review boards, but did indicate that they would be included in final regulations. Final regulations would also require, as a condition of participation "that facilities have affiliations which tie them in with the various modalities of treatment so as to support the development of an organized effective system of delivery of treatment." Finally, authority to a facility to participate in the ESRD interim program did not imply permanent authority for participation in the long-term program.

The preamble made four basic points about interim regulations. First, "ceilings" would be imposed upon reimbursement amounts and covered services, beyond which payment would be made "only if adequate justification is provided." Second, a "grandfather" clause qualified all facilities, provider and nonprovider, engaged in treatment of end-stage renal disease as of June 1, 1973, for participation in the program. Third, a "freeze" was imposed on the expansion of existing facilities and the creation of new facilities; an "exceptions procedure" permitting the increase of treatment capacity was implied. Fourth, interim qualification of treatment facilities required that transplant facilities be part of a Medicare participating hospital, that both transplant and dialysis facilities perform at a reasonable utilization rate each year, that such facilities demonstrate an ability to contribute to access of care in an area, that they contribute to a coordinated system of care and maintain costs consistent with services provided, and that capital expenditures not have been disapproved by a state agency under Section 1122 of P.L. 92-603. Dialysis facilities also had to have arrangements for screening patients for the appropriateness of their treatment.

Five numbered changes were made in subparts A, B, D, and E, of Social Security Administration Regulations No. 5:

- o Sec. 405.104--Entitlement to payment for covered services for dialysis was to begin after the 3-month waiting period, as required by the statute. But entitlement for transplant services was interpreted as beginning in the month of hospitalization in preparation for surgery, if the operation occurred in that or the following month, if that preceded the 3-month waiting period.
- o Sec. 405.116 (g)--Coverage for kidney transplantation was limited to services in those "participating hospitals which on June 1, 1973, have been providing the services and have not substantially increased such services . . ."
- o Sec. 405.231 (g) and (h)--"Medical services" was to include, under durable medical equipment, the rental or purchase of "renal dialysis systems" for use in the home, subject to the deductible and copayment provisions of Medicare. Renal dialysis facilities were limited to those providing services on June 1, 1973. Facilities qualified to participate in the interim program were those in a Medicare participating hospital and free-standing, nonhospital facilities if they met state or local licensure requirements, were under "the general supervision of a physician," had an affiliation with a participating hospital for "back-up care," and agreed to accept assignment of patient benefits.
- o Sec. 405.202--Relative to provider (hospital) reimbursement, the language stated only that "rules may be developed for establishing limits on costs and services above which reimbursement shall be made only upon appropriate justification."

¹The statute was interpreted as silent on transplant coverage, and the above interpretation was deemed consistent with the statute, on the advice of the Office of the General Counsel and with Congressional knowledge and concurrence.

o Sec. 405.502--Given that the normal medical market had been eliminated as a basis for determining "customary and prevailing charges," the regulations stated that "reasonable charges may be defined in terms related to charges or costs prior to July 1, 1973, the costs and profits that are reasonable when the treatments are provided in an effective and economic manner, and/or charges made for other services, taking into account comparable physicians' time and skill requirements." Additional language anticipated, but did not prescribe, ceilings on charges and services.

Three additional points about the June 29 regulations deserve mention. First, in the preamble and throughout the regulations reference was made to the discretionary authority provided to the Secretary of HEW by the statute to limit facility reimbursement and to qualify additional facilities for participation if a need for their services was demonstrated. The extent and limits of this authority were later to be tested through litigation. Second, the explicit bases for determining the allowable reimbursement for facility services and physician services were not stated in the regulations but were left for a later Medicare intermediary letter. Third, the nature and direction of the long-term program was only vaguely suggested by the interim regulations, which constituted little more than a promissory note that final regulations would be forthcoming at some future time. The program was truly "interim."

POLICY PLANNING AND IMPLEMENTATION

It is appropriate to conclude this section with some general observations about the limits and opportunities afforded by the policy planning stage of implementation. First, the administrative system limits planning because many organizational units are involved, each having some legitimate claim to participation. On the one hand, the preexisting division of labor within organizations like BHI, for example, reinforces tendencies to plan for new initiatives in old, familiar ways and by relying upon standard operating procedures. On the other hand, the flux in relations among key organizations, reflecting deeper

structural conflicts as well as the changing tides of politics, as in relations between H and BHI, and internal relations within the Office of the Secretary, creates unforeseen complexity in the policy planning stage. The primary challenge is to seize internal bureaucratic control over the planning stage because decisions reached during this period shape the implementation process for a long time to come.

Second, policy planning is limited by the discontinuity of the policy in question. Discontinuity exists in any movement from the legislative arena to that of administrative discretion, but abruptly enacted legislation exacerbates that discontinuity. In the case of endstage renal disease, moreover, the discontinuity involved a major shift from the statutory authority of the Public Health Service Act to that of the Social Security Act and a related shift in administration responsibility from the PHS to SSA. Medicare experienced two further discontinuities. First, its normal operations relied on the non-Medicare market to generate information for setting reimbursement rates. But in this case, federal preemption of the market eliminated the traditional role played by the non-Medicare market. In addition, Medicare was required to shift its attention from a hospital-dominated delivery system to one in which nonhospital facilities and home care also loomed large. Simply stated, these discontinuities complicated the policy planning task. The opportunity afforded by discontinuity, however, is that of innovation. If there is little reason to maintain consistency with the past, important new policy ground may be broken.

Third, planning is a time-limited process running from the date of enactment to the effective date of a program. Time necessary for education of administrators absorbs time that might otherwise be used for policy planning. More seriously, policy planning tends to absorb almost all planning time, thus squeezing operational planning severely. The latter, moreover, cannot be done in parallel to any great extent because key aspects of operations are contingent upon decisions of a policy nature. Scarce time does confer some advantages: if one is clear about intentions, it may be possible to quickly forge consensus on important path-breaking policy initiatives. It may also permit short-circuiting normal procedures governing rulemaking. On the other hand, scarce time typically forces the deferment of unsettled issues.

Finally, policy planning is normally knowledge or experience-limited if a policy is new. Administrative complexity is always great for regulation-governed entitlement programs. New policy initiatives inevitably mean that data limits are apt to be severe. The opportunities presented by such situations, on the other hand, mean that a program of minimal scope may be possible, later expanding to include complex tasks as more simple ones are mastered. There is also the opportunity to focus on incentives governing the behavior of key actors; such behavior can offset the absence of data about what actually is occurring.

V. THE ESRD INTERIM PROGRAM: LEARNING FROM EXPERIENCE

When the ESRD interim program became effective on July 1, 1973, the Bureau of Health Insurance moved abruptly from problems of planning to those of operations—processing claims, preparing instructional materials, and developing internal administrative capability. But "interim" meant incomplete, and certain policy planning remained to be completed in the operational stage. It also meant temporary, that is, adequate for initial operations but to be made permanent only after being tested against experience. Some policy redesign would be required.

The BHI perspective was that the interim period would be long enough to permit collection of data and the drawing of lessons from operational experience. The H view was that interim status was primarily a result of internal bureaucratic differences and ought to be replaced by permanent policies as soon as possible. The physician community tended to embrace the latter view.

In this section, we analyze the interim program experience in the operational stage. This examination includes the difficulties of operational planning, the start-up problems faced by the program, and the complexities of learning from experience.

OPERATIONAL PLANNING: UNFINISHED TASKS

The time available for planning before a program begins is absorbed mainly in policy planning to the detriment of operational planning. This occurs for several reasons. First, the total available time is determined by political realities, not administrative requirements. Second, policy planning issues—those unresolved by Congress in the formulation of policy and requiring the exercise of administrative discretion—are technically complex and politically very important. They are, consequently, the object of intense conflict, the resolution of which is typically forced only by deadlines. Third, while some operational planning can be done concurrently with policy planning, much of it is contingent upon policy planning

decisions and must be done in sequence rather than in parallel. Given a politically determined planning period and a preoccupation with policy planning, operational planning will be given short shrift. Unresolved operational planning issues will be transferred, therefore, from the planning to the operational stage, thus practically insuring severe start-up problems.

The two major unfinished tasks of the operational planning stage dealt with claims processing and facility certification. Activity in each began in early 1973, but completion was delayed pending the resolution of the policy issues in the interim regulations.

Claims Processing

The administrative core of a federal health financing program is the claims processing system. This system permits beneficiaries to claim their entitlements and providers and suppliers to be reimbursed for their services. An effective system is the sine qua non for insuring that financial resources flow to intended uses. The critical step of operational planning for the ESRD program was developing the "intermediary letter" for guidance in claims processing before the July 1, 1973, effective date of the program.

Timing was important for two reasons. First, government responsibilities in patient care financing changed abruptly on July 1 from minimal to dominant. Second, the government was aware that third-party coverage of medical benefits for end-stage renal disease, especially that provided by private health insurers, would terminate or be severely reduced on July 1. Little margin of flexibility existed for transition problems.

In early June, after the interim regulations had been sent to the HEW secretary, the CRD work group worked feverishly to write the

¹Intermediary letters (I.L.s) are issued for Part A to fiscal intermediaries, and for Part B to fiscal carriers. Many are issued jointly, some separately. Each series—A and B—is numbered consecutively within each calendar year. Although intermediaries and carriers are the primary addressees, I.L.s are widely copied and distributed to all affected parties.

implementing intermediary letter. The letter was released to the public on June 29, 1973, at the press conference announcing the interim regulations. A "questions and answers" document was also distributed. The letter was written in June and technically available on June 29, but advance copies were not distributed until early July and final copies in late July. Little time was available to BHI to educate the intermediaries who would carry the administrative burden of claims processing. Nor was adequate time provided to patients, physicians, facilities, and SSA district offices to understand complex administrative procedures.

The I.L. constituted the authoritative directions about claims processing for the ESRD program; ¹ it relied mainly upon general bill processing methods of Medicare but also introduced some special requirements for ESRD bill processing. These special procedures were to apply to billings for all chronic renal disease beneficiaries regardless of whether the services were provided for renal, general, or a combination of renal and general treatment. ² We briefly summarize here some of the main parts of this 55-page document because these claims processing arrangements demonstrate the level of detail at which implementation controls are applied. They also suggest the enormous potential for implementation problems in the operational stage and anticipate later discussions in this report. ³

¹I.L., Part A, No. 73-25, and I.L., Part B, No. 73-22, "Processing and Payment of Claims for Renal Dialysis and Transplant Services Performed for Eligible Medicare Beneficiaries after June 30, 1973," July 1973. Hereafter, we cite this and other I.L.s according to the following form: I.L. 73-25(A)/73-22(B).

²CRD beneficiaries are entitled to general Medicare benefits in addition to renal benefits.

During the research for this report, the authors frequently encountered individuals both within and outside government who were critical of the BHI institutional concern "for just paying the bills." But inherent in the timely payment of bills are the values of humaneness toward patients and fairness toward facilities and physicians.

The special billing procedures consisted of a mix of old and new arrangements between intermediaries and the institutions delivering care to patients. Hospitals (providers) were to bill the appropriate Medicare intermediary for transplantation services, inpatient dialysis services, or outpatient dialysis services, as they would have before the program. Limited-care dialysis facilities (nonproviders) having out-patient dialysis services were now to bill the intermediary also, even though they would have billed the Medicare carrier before July 1, 1973; the appropriate intermediary was to be the one used by the hospital with which the limited-care facility was affiliated. Hospitals were to use their existing Medicare provider number when billing for services; limited-care dialysis facilities were to be assigned a temporary provider number by the BHI regional office.

The billing procedures for the ESRD program also involved the use of both existing and new forms. Hospitals providing both inpatient and out-patient services were to use existing form SSA 1453 to bill for the former and existing form SSA 1483 for the latter, and monthly submissions were recommended. In addition, a new Medicare Renal Disease Patient History form (SSA 2742) was to be submitted once with the initial in-patient or out-patient billing (whichever came first); this was to generate "basic CRD beneficiary file documentation" for intermediaries' bill reviewing, and also was to be "a basic tool" for gathering statistics on renal disease patients. Another new form, the Medicare Chronic Renal Disease Charge and Service Information form (SSA 2743), was to be submitted with each SSA 1453 or SSA 1483 to provide details on the type of renal service provided and information on charges for such services. Limited-care facilities were to use form SSA 1483 for billing for out-patient services after July 1 (where form SSA 1490 would have been used previously), and were also to submit SSA 2742 and SSA 2743 forms like hospitals. Fifteen single-spaced pages in the I.L. specified how the intermediary should complete and review the information provided on SSA 2742 and SSA 2743.

Patient enrollment, a central process activating the claims processing system, required individuals eligible under Section 299I to

apply to a local SSA district office to establish entitlement to Medicare benefits. After an application had been processed, the individual would receive a Health Insurance card with a claim number, and an entry would be made in SSA's Baltimore-based master record identifying the individual as a 299I beneficiary. Those Medicare beneficiaries over 65 years of age or eligible because of disability status and already entered in the master record would be identified as CRD patients from information provided by the National Institutes of Health registries; a CRD indicator code would be attached to the pre-existing Health Insurance claim number. Patient enrollment was to be facilitated with the submission of a patient history form (SSA 2742) by the treating facility to the intermediary at the time of the first in-patient admission notice (SSA 1453) or first out-patient bill (SSA 1483). But a correct entry into the master record was needed because intermediaries and carriers were obligated to query Baltimore and receive confirmation of a patient's CRD beneficiary status from the master record before paying facility billings submitted for that individual.

In the July I.L., BHI estimated that 10,000 patients would be potentially eligible for Medicare CRD benefits at the outset of the program, 70 percent under Section 2991. There was the possibility, therefore, that not all beneficiaries would have received their Health Insurance cards or be entered in SSA's master record by July 1, 1973. Although the aged and disabled CRD beneficiaries would already have cards and be identified in the master record, they would not necessarily have an indicator code establishing CRD benefit status. Intermediaries were instructed, therefore, to hold all bills from renal treatment facilities until a query could be made to Medicare in Baltimore and a response received with "an indicator code identifying the patient as a CRD beneficiary," a procedure that avoided improper payment by delaying all payments. Temporary query procedures were to be initiated effective July 1, 1973, with the promise that the appropriate indicator code would be established for all CRD beneficiaries by October 1, 1973, enabling the use of regular query procedures thereafter.

Provider reimbursement for dialysis required each hospital to establish a separate renal dialysis cost center, and provided a methodology for those facilities not having such a cost center prior to July 1, 1973. Provider reimbursement for transplantation, however, was to be treated as any other surgical procedure, and thus would not require separate cost accounting.

Transplantation coverage included the cost of kidney donation by living persons. The cost of acquiring cadaver kidneys were covered as services "to make the kidney available to the donee." All physician services to donors were covered; also covered were costs of tissue typing, organ preservation and transportation, and listing patients in a transplant registry.

Facility reimbursement for out-patient dialysis services, whether performed in provider or nonprovider facilities, was to be limited by a "screen." Reimbursement for maintenance dialysis services," the I.L. stated, "will be limited to \$150 per treatment and \$190 per self-dialysis training session; \$145 and \$185, respectively, when laboratory is billed separately." Average costs (or charges) exceeding these limits were to be referred by intermediaries to Medicare and would be disallowed unless justified with documentation.

Nonhospital, limited-care dialysis facilities were to be reimbursed on the basis of reasonable charges, not to exceed the screen. Although the prevailing and customary charges normally constituted the

The "Questions and Answers" paper distinguished between a screen and a ceiling:

[&]quot;Q: Will the programs set ceilings on payment for dialysis treatments performed in facilities?

A: During the interim period, the program will set out in instructions amounts to be used as screens but will not set fixed ceilings above which reimbursement will be automatically denied . . . We have selected screens of \$150 per treatment and \$190 per training self-dialysis session including within the dialysis cost the supervisory services of physicians (\$145 and \$185 respectively, when routine laboratory tests are billed for separately, under certain conditions). Where the average cost of or charge for routine maintenance dialysis is in excess of the stated amounts justification will have to be submitted and approved before the excess amounts will be paid."

basis for establishing an upper limit on Medicare reimbursement, a modification was introduced for the ESRD program: the estimated customary charge was to be calculated from the weighted average of all third-party reimbursements made to the dialysis center for services rendered to the patients during the previous 12 months. If this new rule created a demonstrable hardship, a facility could seek an equity adjustment on the basis of detailed documentation.

Home dialysis equipment was to be reimbursed on the basis of the criteria for reasonable charges for durable medical equipment. Direct contractual arrangements between home patients and suppliers of equipment and supplies were generally acceptable; in these circumstances, patients were to submit bills to carriers. Medicare preferred, however, that suppliers contract for the delivery of home supplies through the facility providing medical support services to the home patient; billing then would be from the facility to the intermediary. The I.L., reflecting earlier policy papers, stated: "Consideration is being given to the development of criteria for determining when home dialysis

These instructions suggest the need for the home dialysis patient to become expert in completing forms as well as in the performance of his or her own treatment.

Carriers were also to process bills received directly from home dialysis patients in accordance with the following instructions:

[&]quot;As a temporary procedure, SSA will permit the home dialysis beneficiary or supplier on assignment to bill on the SSA-1490 for such equipment and supplies, but permanent SSA procedures may require the hospital or limited care facility (LCF) to take over the billing for the home dialysis patient. . . . In processing these equipment and supplies SSA-1490's, the carrier should request a bill of lading (invoice) to provide the detail of supplies furnished. The carrier should obtain information as to the number of dialysis treatments the supplies will cover and document this on the SSA-1490 or on the attachment. Some suppliers customarily ship several months supplies at one time to home dialysis patients. Such supplies should be reimbursed on a monthly basis. It will be necessary to obtain from the beneficiary the number of dialysis treatments received for the month and document this on the SSA-1490 in order to allocate the supplies on a monthly basis. Home dialysis beneficiaries (or suppliers on assignment) should be requested to bill monthly to reduce the number of bills filed for maintenance dialysis."

is indicated and for limiting reimbursement if facility services are provided instead." The durable medical equipment provision and patient relations with suppliers of equipment and supplies would prove to be a source of inequity between home and center dialysis patients.

Intermediaries received "special rules" for billing for a number of services, the most controversial of which pertained to reimbursement for physician services. The physician reimbursement discussion proved to be provocative, if not inflammatory: "Bills for physician personal services in connection with maintenance dialysis should not be allowed without clear evidence of medical necessity." Though physician supervision of a dialysis facility was obviously required, "such services are not considered to constitute a patient-care service, and reasonable charge reimbursement will not be made for such services. Unit supervision is considered a facility service and should be included as a component of the cost or charge for the dialysis."

The "Questions and Answers" document was even more provocative on physician reimbursement:

- Q: How will physicians be reimbursed for their services in connection with the dialysis treatments?
- A: The cost of a physician's supervision, if any, during a dialysis treatment will be considered as part of the overhead of the facility providing the service. When a patient undergoing dialysis treatment suffers abnormal symptoms which require the personal attention of a physician, the program will reimburse the physician for his service on a reasonable charge basis. This will be done through the existing reimbursement mechanism now used under the Medicare program. In addition, with respect to the stabilized patient, the program will recognize one monthly physician's visit for a regular evaluation and two visits a year for a more in-depth review. Beyond these levels, visits will be paid for if justified by the patient's condition; i.e., are 'reasonable and necessary.'

This language about "overhead" was included at the insistence of H, reflecting Klar's influence. BHI assumed these words would be controversial, based on the controversial history of reimbursement of radiologists, anesthesiologists, and pathologists.

The claims processing system converts policies toward reimbursement, coverage, and entitlement into operational reality through forms and procedures that link the provision of treatment with payment for treatment services. In strict administrative terms, the number and complexity of forms, the frequency of their submission, and the number of different relations between institutions in the administrative system create a great potential for implementation problems. Intrinsic in these claims processing arrangements are issues of effectiveness and fairness, for example, the timely flow of payments to facilities, physicians, suppliers, and patients; and issues of equity, such as the comparability of financial burden and benefit received by dialysis patients at home versus those at a center when both are comparable in clinical terms.

In behavioral terms, the claims processing system establishes a pattern of incentives that affects the actions of facilities, physicians, suppliers, and patients in ways that correspond either well or poorly to intended objectives. Whether the resulting behavior approximates the intended objectives depends partly on the knowledge of the interactions between policy objectives and administrative means. It also depends on policy or value choices made within the complex claims processing system.

Moreover, the detailed level at which controls are exercised and incentives established insures that the claims processing system will be understood only by those having a compelling reason to do so--some policy officials and the administrators of day-to-day operations, both government and nongovernment, those facilities, physicians, suppliers, and patients having a direct and substantial stake in the performance and output of the system. The system is, and will remain, largely inaccessible to others without an incentive to master its complexity.

Facility Certification

The interim solution to the certification of ESRD facilities was to include all existing facilities into the program, impose a freeze on expansion or creation of new facilities, and provide for exceptions to the freeze. Even an interim program needed to identify

facilities, however, and that unfulfilled task of operational planning was carried into the operational stage.

Facility Identification. Making a list is not always easy, since it involves establishing criteria for including and excluding items. In 1970, Section 907 of P.L. 91-515¹ required the HEW Secretary to establish and maintain a list, or lists, of U.S. facilities "equipped and staffed to provide the most advanced methods and techniques in the diagnosis and treatment of heart disease, cancer, stroke, or kidney disease." Responsibility for compiling these lists fell to the RMPS, which, after consultation with the medical community, identified the following problems: Would such a list be inclusive or exclusive? How would it be utilized and by whom? What were the legal and resource allocation implications? What level of excellence was to be specified in the criteria for compilation? What were to be the bases of listing—capacity or performance? What procedure was to be used in the development of the lists? What kind of data were to be compiled?

The temporizing solution RMPS adopted was to ask expert committees to develop criteria for listing facilities that were inclusive rather than exclusive and sensitive to local factors. For endstage renal disease, a committee of the NKF, under an RMPS contract, prepared a report dealing with criteria for optimal treatment facilities. Essentially the same committee later prepared a report on optimal criteria for treatment facilities for the Joint Commission on Accreditation of Hospitals, also with RMPS contract support. Although neither report listed dialysis and transplantation facilities, RMPS did compile such a list during its support of these initiatives.

¹Public Law 91-515, The Heart Disease, Cancer, Stroke, and Kidney Disease Amendments of 1970.

²National Kidney Foundation, "The Optimal Facilities Necessary for Diagnosis and Management of Patients with End-Stage Renal Disease," prepared for the Regional Medical Programs Service, June 13, 1972.

Kidney Advisory Committee, Joint Commission on Accreditation of Hospitals, "Optimal Criteria for End-Stage Kidney Disease Care," Journal of the American Medical Association, Vol. 226, No. 1, October 1, 1973, pp. 45-49.

In January 1973, the DSO asked both RMPS and the Comprehensive Health Planning Service (CHPS) for help in identifying facilities in their jurisdictions. RMPS and CHPS responded with a list in February, which DSO then distributed to BHI Regional Offices and to Medicare state survey agencies. The latter were asked to check the list against their own knowledge of the local situation.

annual survey conducted by state survey agencies, and this approach was how DSO was proceeding. Discussions on a presurvey form, however, revealed problems: facilities were to be asked for information useful in drafting the conditions of participation, but conditions of participation had not been agreed upon and thus derivative questions could not be formulated. There was interest for a time in staffing patterns of "satellite" and "free-standing" dialysis centers, but the absence of definitions of these terms stopped such a request. An underlying difficulty was the assumption by BHI that the poor performance of some facilities would cause them to be rejected from participation; but there was no definition of "poor performance."

Moreover, as July 1 neared, concern also grew about how patients would be transferred from a facility denied participation to one that was certified. The interim regulations temporarily avoided the problem.

Facility identification persisted as a problem into the fall. In mid-June 1973, BHI sent an Identical Memorandum (I.M.) to its regional offices, with a list of facilities in their regions and a request to identify all facilities providing dialysis and transplant services as soon as possible. A second I.M. was sent in July, instructing regional offices about how to process facility "expressions of intent" to deliver services and how to allow participation. A

¹I.M. 73-87, "Identifying Kidney Treatment Facilities and Ascertaining Their Intent Regarding Medicare Participation," June 1973. An "identical memorandum" is the communication means between BHI and its regional offices.

²I.M. 73-110, "Processing 'Expression of Intent' Forms Received from Kidney Treatment Facilities," July 1973.

letter to state survey agencies, also sent in July, indicated that conditions of participation would not occur for several months, noted the regional office identification effort, and suggested referral of all questions to the regional office. In October, another I.M. asked regional offices for a status report on facilities, stating: "Our records show a substantial number of treatment kidney facilities whose Medicare status has not yet been clarified." The problem was to continue for some time.

Exceptions Criteria and Procedures. In Rockville, Maryland, meanwhile, within BQA the barely organized ESRD unit was beginning to develop the exceptions criteria and procedures for expanding existing facilities and creating new ones. Dr. Samuel W. Kidder, with two RMPS physicians, began drafting these materials in mid-August. He completed and circulated them within H and BHI, and received comments in September. The draft was also sent to the ten HEW Regional Health Administrators and in late September, BQA held a working session for regional office staff to review the entire process in detail. The Assistant Secretary for Health approved the materials in November; Office of Management and Budget clearance came in early December; and the exceptions criteria and procedures materials were distributed in mid-December.

The key document was an interim period exception criteria statement, which dealt respectively with transplantation and chronic

¹BHI Letter to State Agencies, No. 186, "Certification of Facilities Providing Renal Services," July 1973.

²I.M. 73-163, "Reporting on the Status of Kidney Treatment Facilities," October 1973.

The package included a cover memorandum from the director of BQA to the ten regional health office administrators; guidelines for use of the interim period exception criteria; definitions; an exception procedures flowchart; model letters for approval and denial of exception requests; instructions to facilities for completing an application for an exception; the application itself; a memorandum from the Bureau of Health Resources Development to state and areawide Comprehensive Health Planning agencies discussing their involvement in the process; the June 29, 1973, interim regulations; a form for the Regional Office review of applications; and, finally, a model letter to the state and area-wide CHP agencies in the applicant's area.

maintenance dialysis. Each section elaborated the language in the preamble to the interim regulations as the basis for the criteria. For transplantation, the criteria to be met included the following: although 25 or more transplants per year were not required, this level was suggested as a possible long-term requirement, and "a reasonable scale of operations" was set at 15 per year; "capacity for high performance" required minimal personnel and service levels; "contribution of access of care" would be based upon the documentation of patients available for transplantation who could not expect treatment from another transplant facility, and the absence of any other facilities better qualified to meet the needs of such patients; "cooperation in a system of care" meant participation in a recipient transplant registry and an organ procurement and preservation program.

For chronic maintenance dialysis facilities, the following criteria were required: an acceptable utilization rate of at least two dialysis stations, each operating at least five sessions per week; minimal personnel and service levels; a "needed contribution to access of care" criterion identical to transplant facilities; a "patient review mechanism" criterion requiring each facility to review its patients for transplantation and self-dialysis training, make a formal recommendation about the appropriate treatment to the referring facilities, and reevaluate each patient annually, prior to the establishment of medical review boards. Free-standing dialysis facilities were required to have an affiliation with a participating hospital for emergency back-up care, necessary vascular access procedures, selfcare dialysis, self-dialysis training and certain other minimal service requirements.

Facilities were to request an application kit from the BHI regional office, complete the forms, and submit them concurrently to the 314B (area) and the 314A (state) Comprehensive Health Planning (CHP) agencies for a review within 60 days. The CHP agencies would transmit the completed forms to the regional office, as would the provider, where they would be processed by the regional health administrator within 10 days. An information copy would then go to BHI's central office and a review copy to the BQA central office and a joint BHI-BQA adjudication work group.

The joint work group would process the application, recommend action to BHI for its decision, after which the BHI central office would transmit that decision to the BHI regional offices for notification of the appropriate regional office units, health planning agencies and the facility. If the request was approved, a letter conveyed that decision and assigned a provider number to the facility. In the case of a denial, the letter set forth reasons for the action.

These criteria and procedures, distributed in December 1973, constituted the basis for the interim program for reviewing requests to establish new or expand existing facilities. Because of the importance of certification decisions, HEW legal counsel to SSA advised BHI that these procedures should be published in accordance with the Administrative Procedures Act. Consequently, on October 4, 1974, the exception procedures and criteria were published in the Federal Register as a Notice of Proposed Rule Making, and on April 22, 1975, as a final rule.

START-UP PROBLEMS

Practically all government programs experience start-up problems in their initial months and even years of operation. Some problems are resolved with few consequences except delay and inconvenience, 3 but others constrain future policy and operational decisions, and still others force explicit policy revision. Here we examine two problems: claims processing and physician reimbursement.

Claims Processing Problems

In its simplest form, claims processing involves billing and payment for provided services. But the ESRD operational experience

¹39 Federal Register 35811, "Facilities Providing Treatment for End-Stage Renal Disease: Interim Period Qualification and Exception Criteria," October 4, 1974.

²40 Federal Register, "Interim Period Qualification and Exception Criteria to be Applied to Services of Facilities Providing Treatment for End-Stage Renal Disease," April 22, 1975.

³Inconvenience may be substantial in the case of life-sustaining efforts like the ESRD program.

in 1973 and well into 1974 was not simple. Not until February and March of 1974 did facilities across the country begin to receive regular and full payment for ESRD services they had provided since the inception of the program!

The cash-flow problem had its roots partly in the difficulties of identifying facilities, and partly in the enrollment of CRD beneficiaries and the establishment of Health Insurance claim numbers for them in the master beneficiary record. Without a number in the record, an intermediary could not receive a prompt response from Baltimore to a beneficiary identification query and thus was not authorized to make payment for services. The data in Table 12 provide the story. On September 8, 1973, 10,752 CRD claims had been filed, of which only 36 percent (3,924) had been processed. A master beneficiary record had been established for only 11 percent (1,180) of these claims, though the records of an additional 1,726 aged or

Table 12
ESRD PATIENT ENROLLMENT DATA, 1973-1974

Item	9/08/73	10/19/73	12/14/73	3/74
CRD claims				
filed (cumulative)	10,752	10,547	13,122	14,780
Processed Allowances Denials	3,924 (3,637) (287)	8,176 (7,380) (796)	10,939 (9,722) (1,217)	13,345 (11,720) (1,625)
Pending	6,828	4,371	2,183	1,435
Health Insurance Master Records Established:	2,942	6,717	10,045	14,211
Established.	2, 942	0,717		
CRD allowances Eligible ^b	(1,180) (1,762)	(4,763) (1,954)	(7,845) ^a (2,200)	(9,515) ^a (4,696)

SOURCE: From Volumes I, II, III, and IV, "The Chronic Renal Disease Report," SSA/BHI/CRD, September 27, October 26, December 28, 1973, and March 1974.

^aThe use of temporary eligibility procedures accounted for 1,472 and 1,386 of these records, respectively.

^bPatients entitled to CRD benefits based on other provisions than Section 299I, that is, those 65 or over or disabled for whom master beneficiary records had been annotated as CRD-eligible.

disabled had been annotated with the CRD beneficiary designation. Over the next six months, the proportion of CRD claims processed to those filed steadily increased to 90 percent, and the proportion of CRD records established to CRD claims filed climbed to 64 percent.

The cash-flow problems caused a roar of protest. Senator Henry M. Jackson (D., Wash.), for example, complained in late November that the ESRD program "has not really gotten off the ground. . . . Many physicians have not been paid for their services for months; many hospitals in which they serve have not been reimbursed for months; many physicians cannot put their patients on home care therapy because they are uncertain whether these patients will in fact have their care paid for, and the physicians do not want their patients to suffer great economic loss."

Senator Vance Hartke (D., Ind.), principal author of Section 299I, was the most vocal critic in the Congress. In remarks to the Senate, he described the February 1974 situation as chaotic:

As of February 8, 1974, over \$22 million has been paid to health care providers under the kidney disease program. As admirable as this figure may be, it is only one-fourth of the amount which we had estimated would have been paid during the first 9 months of the program. In addition, if the experience in Indiana is any indication, this \$22 million represents only two-thirds of the total amount which has been billed to date by health care providers.²

Hartke distributed a questionnaire to state hospital associations, and the responses revealed numerous severe problems. The Kuakini Hospital and Home, Honolulu, Hawaii, for instance, wrote:

The hemodialysis claims were first billed in July of 1973 and the very first payment of these claims was received in

¹ 119 Cong. Rec. 38973 (1973).

²120 Cong. Rec. 5230 (1974).

Hartke published the results of his questionnaire in successive issues of the *Congressional Record* on August 1, 7, 13, 15, 20, and 21, 1974; see 120 *Cong. Rec.* 26262-26270, 27137-27145, 28080-28085, 28524-28535, 29099-29101, 29550-29551 (1974).

December of 1973. . . . An example picked at random from our books shows that a patient receiving treatment on November 19 to the 25th, 1973, had to await the report of eligibility from Baltimore until February 4, 1974. Only then could the hospital bill the patient.

An article reprinted from the Springfield (Illinois) Register revealed problems common to many hospitals:

Illinois hospitals' main problems appear to be getting Medicare cards issued by Social Security to patients so they are eligible and then collecting for treatment given to them.

Memorial Medical Center provides services eligible for federal reimbursement at the rate of approximately \$100,000 a month, according to Russell Beckwith, its chief financial officer.

So far the medical center has sent in bills totaling more than \$400,000, mainly for outpatient renal dialysis done between July 1 and February 1. The medical center has received only one partial payment of \$132,000.

It is an ironic, perhaps inescapable, fact of implementation that the Congressional author of a hastily drafted amendment could, some months later, be attacking the bureaucracy for its incompetence. But they also serve who only suffer in silence.

Early in 1974, Mr. Jordan Ringel, Chairman, and Dr. James C. Hunt, President of NKF, wrote Secretary Weinberger, about the "major concerns" of the members and friends of NKF with implementation of the ESRD program. They complained of a "deterioration of services and quality of care": some facilities had not been certified; nongovernment third-party payers had abruptly terminated coverage of renal disease; orderly expansion of facilities had been curtailed by the freeze on facilities; current reimbursement, when available, was not adequate to maintain existing programs; dialysis centers had reduced personnel to reduce costs; the patient-physician relationship had been disrupted by the refusal to reimburse physician supervision; Medicare intermediaries had refused payment for a variety of reasons; and patients preferring home dialysis had experienced a loss of the

"normal flow of medical supervision or supplies." But the disruption of cash flow was the central concern.

Medicare responded to these problems by instituting, in late September 1973, an emergency payments procedure that allowed an intermediary to pay bills in cases when CRD beneficiary status could not be established by the routine central office query process, but patient entitlement could be verified through the appropriate SSA district office. In addition, BHI sought to clarify the initial intermediary letter regarding bill review for excessive dialysis charges, acute (emergency) dialysis charges, and coverage of home dialysis supplies when included in a package of supplies.²

One year after the program began, many of the claims processing problems had been resolved and procedures had become routine. But this occurred only after substantial distress had been experienced by many patients and a serious cash-flow problem had been created for facilities. A variety of factors contributed to these problems during the initial year. Instructions were complex, late in distribution, inadequately explained, and not supplemented by training. Forms were new, numerous, detailed, and often lacked a clearly perceived rationale to facilities and intermediaries. Procedures were also new and complex; they were often interrelated and disruptive of preexisting patterns. The volume of ESRD claims was low relative to normal Melicare claims, thus not justifying much intermediary personnel time. Personnel in many SSA district offices were retiring rather than contending with the forthcoming problems of the Supplemental Security Income program, a radical new departure for SSA, whose anticipated volume dwarfed that of the ESRD program. The administrative system involved many new organizational entities, many of

Several physicians reviewing this report in draft indicated the persistence to the present time of cash-flow problems due to various factors; for example, delay in establishing patient entitlement status for home dialysis patients.

²One means of clarification was the Chronic Renal Disease Report, four issues of which appeared from September 1973 through March 1974. These reports provided information on the status of CRD enrollments, and discussed issues of coverage, reimbursement, facility qualification, claims processing, and other matters of general interest.

which were unfamiliar to each other, having weak working relationships. In some cases, there was misunderstanding by the medical community of the legitimate requirements of a federal government medical benefit program. In other cases, the misunderstanding was the government's failure to comprehend the legitimate requirements of medical practice. Throughout the entire system, there was little education and training, little communication adequate to the administrative task. It is no surprise that start-up problems were encountered.

Physician Reimbursement

The single most inflammatory feature of the interim program was the provision for reimbursement of physicians treating dialysis patients. The interim regulations had been silent on this matter, though the "Questions and Answers" had stated: "The cost of a physician's supervision, if any, during a dialysis treatment will be considered as part of the overhead of the facility providing the service." (Emphasis added.) The detailed statement of interim policy governing maintenance dialysis was set forth in I.L. 73-25(A)/ 73-22(B). First, maintenance dialysis was "generally not considered" to require a physician's personal service. Second, no more than a small percentage of patients--"on the order of 5 percent"--required physicians' personal services during routine dialysis. Bills for such services should document their medical necessity, and be disallowed without "clear evidence" of necessity. Third, though interim regulations required general supervision of a dialysis facility by a physician, supervisory services were not to be considered a patient care service but a facility service and included in the facility charge for the dialysis. Fourth, reimbursement without documentation would be allowed for one office visit per patient each month, and two indepth evaluations each year. Any payment beyond these limits should be made only if documentation established that "an abnormality" required them. Finally, physician supervision of self-dialysis and home

¹I.L. 73-25(A)/73-22(B), July 1973, pp. 8-9.

dialysis training was also to be treated as a facility cost and not as a physician service to patients.

The insult to physicians was stated this way: "Fee-for-service reimbursement for physicians' services in an out-of-hospital (as well as in-hospital) dialysis center shall be made only when an identifiable service to the patient is performed, e.g., the patient goes into shock, experiences severe chest pains, etc. Supervision by a physician of the dialysis 'run' is part of the facility cost for the dialysis and is not reimbursable as a separate charge." Alteration of existing practice was bad enough; that the government should now attempt to specify how doctors should practice medicine was too much.

The protest began immediately. On Friday, July 13, 1973, in a hotel near Chicago's O'Hare International Airport, about 60 physicians from around the country came together. Though some were academicians, many were practicing physicians having little association with academic medicine. The physicians at this "Black Friday" meeting, however, were not NKF influentials and were motivated both by their strong reaction to government policy and to the near-monopoly position on advice to the government which NKF had sought to assume.

One result of the July 13 meeting was the formation of a new organization—The Physicians for Renal Replacement Therapy (PRRT). In its position paper, the PRRT criticized the intermediary letter for an approach to implementing Section 299I that would "impair the successful delivery of nephrological care to end-stage renal patients." Under "The Physicians' Right to Fair Compensation," PRRT registered "strong protest" to the physician reimbursement provisions of the I.L. Numerous medical problems required that physicians "continually monitor a patient undergoing hemodialysis," and "physicians must be available during dialysis treatment for numerous services in addition to acute medical emergencies." "Assuming that all parties would agree that the physician is recognized as medically indispensable for the delivery of continuing dialysis treatment to the end-stage renal

¹I.L. 73-25(A)/73-22(B), p. 24.

²Position Paper of Physicians for Renal Replacement Therapy, Chicago, Illinois, n.d. (1973).

patient," the paper continued, "then it follows that he should be fairly compensated for his service." PRRT concluded that fee-for-service physician reimbursement should not be abandoned, that direct payment should be made to physicians attending patients, and that reimbursing physicians through facility "overhead" was detrimental to patient care. The organization expressed its willingness to work with HEW "in devising a fee schedule or other appropriate method of solving the problem of fair physician compensation.

HEW heard from all quarters of the physician community about the full range of ESRD implementation problems, but especially about physician reimbursement. On September 18, 1973, Assistant Secretary Edwards, Klar, BHI, and BQA representatives, met with the National Kidney Foundation, the American Medical Association, the American Society of Internal Medicine (ASIM), the Physicians for Renal Replacement Therapy, and the National Association of Patients on Hemodialysis and Transplantation. The mutually agreed-upon agenda for the meeting dealt with interim program reimbursement alternatives, exceptions criteria and procedures, and long-term program conditions of participation.

The physician community was not entirely unanimous on physician reimbursement at this time. The NKF August White Paper had referred to "utilizing a fee-for-service method" but went on to specify upper limits for monthly payments for several types of physician services. The ASIM endorsed a "fee-for-service" approach and direct payment to physicians and strongly urged HEW to "not place the physician in the position of bargaining with a hospital for the professional component of dialysis service.

HEW officials, then under substantial criticism, reacted defensively at the September 18 meeting. Edwards made a brief formal

This defensiveness was apparent in a memorandum Klar wrote beforehand. The purpose of the meeting, he stated, was "to provide these groups with the opportunity to summarize, clarify, and emphasize their views and recommendations on the kidney disease treatment program. This meeting is not to be a forum to discuss the issues; instead, they will present and we will listen." (Emphasis added.) Memorandum, from Special Assistant for Health Policy Development, to Addressees, "Forthcoming Meeting on the Kidney Disease Treatment Program of Medicine—Agenda and Background Materials," September 13, 1973.

presentation, but remained aloof during the discussion and left early. Klar chaired the rest of the meeting, and claims to have solicited comments on two physician reimbursement alternatives (an inclusive payment for each dialysis episode and the same for a patient month) and on two facility reimbursement alternatives. Physicians present, like Dr. John Sadler of the University of Maryland and Dr. Stuart Kleit of the University of Indiana, recall his dominance of the meeting, his insistence that nephrologists could not agree on the amount of needed supervision, and his unwillingness to admit the need for change from existing policy. The acrimonious encounter served mainly to alienate the physician community from H.

The physician community, out of disenchantment with H, turned to BHI. Officials there sought to explain and defend the interim policy, while simultaneously indicating a willingness to review it. In late October, BHI published its rationale for the policy: "The purpose of the brief guidelines in the intermediary letter was to differentiate between types of unusual or nonroutine circumstances for which a separate change could be recognized and the varying combination of other physicians' services which would normally be included as part of the maintenance dialysis charge." Supervisory services were illustrated for routine maintenance dialysis, as were patient care services for complications and nonroutine situations. Administrative services were distinguished from supervisory services. And, responding to the external criticism, BHI announced that the policy was under continuing evaluation and alternative approaches were being considered.

Wolkstein, who had suggested the possibility of a monthly capitation payment for physicians in April, was receptive to the physicians. Discussions focused quickly on the retainer concept of payment, though it was clear that a different term would be required to avoid veto by the American Medical Association. First, a "global fee" was considered

¹BHI, "The Chronic Renal Disease Report," Volume II, October 26, 1973, pp. 4-5.

²BHI, Office of Program Policy, "Statement of Issues, Alternatives, and Background on Reimbursement Policy for Hemodialysis, Kidney Transplant and Physician Services under Section 299I of P.L. 92-603, April 1973.

then a "fee for a collective unit of service," and finally the "alternate method" was agreed upon.

Within H, Klar devoted himself to developing policy for the longterm organizational issues and to dealing with both facility and physician reimbursement issues. He set forth his views on reimbursement at length in a December 19 memorandum to Edwards, fully thirteen pages devoted to physician reimbursement. He sought to differentiate six types of physician services provided to maintenance dialysis patients--hospital care, illness care, acute dialysis care, routine dialysis care, monitoring, and availability. The discussion, however, neither defined these categories nor specified the underlying bases for differentiation among them, even though expressing the hope that some standards of acceptable medical practice could be established relative to them. The absence of consensus on professional standards and the inadequacy of existing data led Klar to conclude that it was "inappropriate" to specify a single set of physician services for reimbursement. Rather, those services to be reimbursed should be those "usual and ordinary" to a dialysis episode--services illustrated but not defined. The memorandum made the issue more complex without developing or recommending a preferred course of action.

The Klar memorandum was distributed among the H agencies. BQA, in its response, stressed the importance of including BHI "in deliberations concerning reimbursement policy, since this agency has long and extensive experience in this area of policy development." The BQA critique suggested several specific changes, which were discussed in late December and incorporated in a January 4 revision. Assistant Secretary Edwards then transmitted these revised reimbursement proposals to Social Security Commissioner James Cardwell, along

¹Memorandum, from Director, Office of Health Financing Policy Development, to Assistant Secretary for Health, "Kidney Disease Treatment Program of Medicare--Reimbursement Policy Issues--ACTION," December 19, 1973.

²Memorandum, from Associate Administrator, Health Services Administration, to Acting Director, Office of Policy Development and Planning, H, "BQA's Comments on Reimbursement Policy Issues (December 19, 1973 Memorandum to H) on the End-Stage Renal Disease Program," December 26, 1973.

with proposals on organization of facilities and services, requesting his "formal review and concurrence." Cardwell, in a memorandum prepared by BHI, responded in early February, quickly identifying "a number of problems" with Klar's memorandum in two brief pages. He dismissed Klar's concern for facility reimbursement by noting that "many of [Klar's] options . . . for maintenance dialysis would require a change in the law." More to the point, facility reimbursement was not the problem; the problem was physician reimbursement. Cardwell wrote:

I do believe that we need to decide as soon as possible upon an alternative method of reimbursing physicians for renal dialysis services—one which not only responds to the failure of the present method to gain acceptability because of its reimbursement through the institution but also provides a better incentive toward home dialysis than does the current method. I would not, however, cancel out the current method in providing such an alternative. . . . Aside from the confusion and dislocation that would result if this approach is barred, the method has a number of advantages, one of which is that it provides some inducement to facilities to be interested in keeping physician payments within reason. Moreover, there is the advantage of being able to require assignment if this method is retained.²

Cardwell argued for an "all inclusive" payment: this was the basis for many nephrologists' billing procedures before Medicare; it would be easy to administer; and it provided greater ability to control costs. A set of SSA draft instructions, forwarded to Edwards on December 21, Cardwell suggested, constituted a conceptual basis for reimbursing physician services.

¹ Memorandum from Assistant Secretary for Health to Commissioner, SSA, "Proposed Policies on Chronic Renal Disease Program of Medicare," January 15, 1974. Indicative of the bureaucratic skirmishing going on, SSA was asked to respond by close of business, January 18.

²Memorandum from Commissioner of Social Security to Assistant Secretary for Health, "Proposed Policies on Chronic Renal Disease Program of Medicare (Your Memo, 1/15/74)—INFORMATION MEMORANDUM." February 6, 1974.

Klar, further clarifying his earlier memoranda, posed three issues for Edwards in a mid-February revision:

- o Should physicians be paid through facility reimbursement or by a separate fixed charge?
- o If the latter is preferred, should the charge be "an aggregate monthly charge" or a charge per dialysis?
- o Should assignment remain voluntary or be required as a condition of the monthly retainer approach?

Edwards indicated his preference for separate physician reimbursement on a monthly retainer basis, while maintaining voluntary assignment. The Assistant Secretary's decision was distributed within the Office of the Secretary, HEW, along with the SSA comments, for concurrence by February 19.

By mid-March 1974, a departmental proposal on reimbursement issues of immediate importance had been developed and joined to a second proposal for organizing the long-term ESRD program into networks and establishing medical review boards. These two proposals were incorporated into a single package and transmitted by Edwards to Secretary Weinberger for his approval. The package became the basis for the final policies announced in April. Overall, HEW was driven by the need to take corrective action on reimbursement issues in response to external criticism, to establish medical review boards and minimum utilization rates in response to the statute, and to establish Secretarial policy for the ESRD program in response to a need perceived by H.

The experience of the medical community from July 1973 onward was like a sudden plunge into cold water. On physician reimbursement, they were outraged by the language of the government's policy, the government's arrogance in dictating how they should practice medicine,

¹The organizational issues of medical review boards, minimum utilization rates, and ESRD networks are analyzed in Section VI.

and the abrupt, if not arbitrary, manner in which the government acted. The conflict between H and BHI disturbed them: though drawn to the BHI professionals and antagonized by H, they were confused about where authority and power actually resided. Led to expect rapid progress in resolving outstanding policy issues by overoptimistic predictions about when the interim program would become "final," they grew increasingly impatient as the months passed and as they encountered what they considered to be a delay strategy by HEW.

Physicians in New Jersey and California became so frustrated that they filed suit against the federal government. Dr. John Capelli, in a latter to the Board of Directors of the Renal Physicians Association (RPA), 1 recounted the events leading to the litigation: 2

- 1. A New Jersey RPA Position Paper on P.L. 92-603, July 5, 1973, was forwarded to HEW;
- A statement on physicians services, adopted August 1, at the request of Senator Harrison Williams, was forwarded to HEW;
- 3. A meeting at HEW, August 8, resulted in assurances of immediate changes in physician reimbursement;
- 4. The September 18 meeting at HEW resulted in assurances of change within weeks;
- 5. An October 15 letter to Secretary Weinberger threatened suit on November 1, if immediate action was not forthcoming;
- 6. A meeting at HEW, October 30, on medical review and physician reimbursement resulted in assurances of a change in the latter within three weeks, and revised regulations by January 1, 1974;
- 7. Litigation was consequently withheld by the New Jersey RPA for 30 days, and the RPA lawyer wrote Secretary Weinberger of this decision;

On November 18, 1973, the Renal Physicians Association was created as a successor organization to the Physicians for Renal Replacement Therapy.

²Quoted in New York State Renal Physicians Association Newsletter, March 7, 1974, pp. 5-7.

- 8. Officials of SSA-BHI informed New Jersey RPA on November 29 that an intermediary letter had been prepared and was being distributed for advance consultation; physician reimbursement was to be on a "retainer" basis;
- 9. As a result of the above, the New Jersey RPA suspended all plans for litigation in expectation of an HEW policy revision by mid-January, to be implemented by February 1;
- 10. On January 6, Capelli attended a meeting at SSA at which it was "privately mentioned" that H had rejected the retainer idea and was preparing a counterproposal;
- 11. On January 22, Capelli and others received a letter from Klar saying that no decision had been made about physician reimbursement, but that options were still being considered;
- 12. On February 6, Capelli's discussions with both H and BHI convinced him that nothing definitive was forth-coming any time soon;
- 13. On February 13, the New Jersey RPA reviewed events, voted unanimously to initiate suit; and
- 14. Directed its legal counsel to coordinate litigation with the California Association of Nephrologists.

On March 4, 1974, the New Jersey Renal Physicians Association filed suit against Casper W. Weinberger and others in the U.S. District Court, Newark, New Jersey. The Association of California Nephrologists did the same in the U.S. District Court, Central District of California, Los Angeles. 2

¹Scaiella et al., v. Weinberger, No. 74-300 (D.New Jersey, filed March 4, 1974).

Hawkins et al., v. Weinberger, No. 74-597 (C.D.Calif., filed March 4, 1974).

The New Jersey petition asked the U.S. District Court to void the July 1973 intermediary letter and compel the government to continue relying upon the "usual and customary" methods of reimbursement until new methods could be adopted by proper procedures. The plaintiffs argued, first, that no legal basis authorized HEW "to supplant with its own medical formula the consideration by renal physicians of their patients' need and alter abruptly its long settled method of paying for their services." The I.L. was a "startling departure" from the Medicare policies and procedures that existed from 1965 to 1973; HEW could not depart from its previous norms without "clear public explanation," and nothing in the Section 299I or its legislative history "could serve as a prop" to the unpublished requirement for physicians to negotiate with facilities because their services were part of facility overhead. Second, the brief argued, no rational basis existed for the requirement: government had no right to a medical philosophy; even if it did, its position was "grossly unreasonable and unrealistic," because patients were deprived of their right to choose a physician; and physicians were deprived of just compensation without due process. Finally, the argument went, the minimal due process requirements of the Administrative Procedures Act included prior notification by the government to interested parties of intent to issue rules and opportunity for those parties to participate in decisionmaking by filing objections. These requirements had not been met.

Within two weeks after the suits were filed, Assistant Secretary Edwards sent Secretary Weinberger the package of materials that became the final policies. Included within these materials was a proposal to modify physician reimbursement policy by retaining the initial arrangement of payment through the facility; but now an optimal "alternate method" would be added, which permitted physicians to be paid a monthly capitation fee per patient, subject to the requirement that all physicians in a given facility had to elect the same procedure. Voluntary assignment was retained. The Secretary approved

the recommendation. The decision was announced at a New York press conference on April 17, 1974.

What caused HEW to act? Two diametrically opposed explanations exist. Klar, on the one hand, categorically states that the final policies were a result of internal HEW decision processes, admittedly slow, but certain nevertheless. Others, like Capelli, are persuaded that HEW would not have acted without the threat of litigation. The most likely explanation is that internal processes and external pressures were both at work and their interaction led to revision of physician reimbursement policies. But generally speaking, relations between HEW, and especially H, and the physician community had reached such an adversarial state that most observers believe that litigation forced the government to act, regardless of where the facts lie. This perception may have been one of the higher costs of this episode.

Although the final policies authorized a monthly payment of physician reimbursement, it was not indicated how this was to be done. The task of converting Secretarial policy to operational guidelines was done in two working sessions in Baltimore in late April and early May. A line-by-line review of a draft intermediary letter ironed out remaining policy issues. BHI issued the instructions in a letter distributed in June 1974. The monthly payment was limited to a charge of not less than \$8 nor more than \$12, multiplied by a "conversion factor" reflecting "not only the frequency of services which are customarily provided to maintenance dialysis patients but also the complexity of the specialized care rendered by nephrologists." The

Department of Health, Education, and Welfare, Final Policies: P.L. 92-603, Section 299I, End-Stage Renal Disease Program of Medicare, Office of Policy Development and Planning, Office of the Assistant Secretary for Health, April 1974. (Hereafter Final Policies.)

²The BHI representatives included Wolkstein and his staff; physicians included Drs. Arvin Weinstein, Stuart Kleit, John Sadler, Chris Blagg, and John Capelli. Klar did not attend, but sent two subordinates.

³I.L. 74-29(A)(3), "Alternative Reimbursement Method of Monthly Payments to Physicians for Services Rendered to Patients on Maintenance Dialysis," June 1974.

conversion factor was to be 20 for physicians treating patients in centers and 14 for physicians treating home patients. The monthly retainer, then, ranged from \$160-240 for the former and from \$112-168 for the latter.

POLICY PLANNING: LEARNING BY DOING

Policy planning is seldom if ever completed during the formal planning stage, and the ESRD program was no exception. Some policy issues are secondary to those essential to getting an operational program under way, while others are just not fully understood until illuminated by operational experience. Here we consider three policy issues not resolved before issuance of the interim regulations: the relationship of Medicare's ESRD program to the corresponding Veterans Administration program, the policy toward home dialysis, and the matter of cost containment.

The Veterans Administration

The VA hospital system is the largest centralized hospital system in the world. But many of its hospitals have, as a result of VA policy, affiliations with major medical schools. These affiliations often lead to complex institutional relationships between VA and non-VA hospitals, and this was the case in the treatment of kidney disease.

One such relationship existed in Indianapolis between the Indiana University Medical Center and the local VA Hospital (or VAH).

Dr. Stuart Kleit, chief of the renal division at the center, developed a comprehensive dialysis and transplantation program before 1972 for both veterans and nonveterans that involved sharing facilities between the center and the Indianapolis VAH. In early 1973, he wrote BHI expressing his concern about the legal inability of Medicare to reimburse nonveterans for medical services provided in federal hospitals. He endorsed Section 299I, but feared the consequences of dismantling the kidney transplantation program, based in the VAH, and the effects on the dialysis patients if nonveterans treated in the VAH could not be reimbursed by Medicare. Kleit was not alone; about 20 other comparable situations existed across the country.

The magnitude of the national problem at the time is unclear. In early 1973, it was estimated that the VA's hemodialysis program was responsible for over 2,000 patients in 44 dialysis centers. This included 806 patients being treated in centers, 173 in home training, 766 on home dialysis, 26 in satellite dialysis settings, and 44 receiving peritoneal dialysis. Under the "Contract" program, it was estimated that an additional 200 veterans were being treated in non-VA hospitals. Another 161 patients were known to be on waiting lists for treatment. But under "sharing agreements" with non-VA hospitals, 16 VA hospitals were then dialyzing 61 nonveterans, suggesting that the problem was not a huge one.

Nevertheless, the relationship of the VA program to the Medicare ESRD program was a policy issue of some importance, one which required nearly two years to resolve. Prolonged interagency negotiations involved numerous written communiques between VA and HEW officials, including the VA Administrator and the HEW Secretary, and many, many meetings. And the policy issues consisted of a "witches' brew" of legal, political, and administrative considerations.

On February 22, 1973, BHI's Wolkstein wrote Francis J. Frankina, director of the legal and legislative staff of the VA's Department of Medicine and Surgery, raising the issues of concern to Kleit and more broadly of concern to Medicare. This precipitated an exchange of correspondence between the VA and HEW general counsels that defined the central issues.

John J. Corcoran, VA General Counsel, in a March 29, 1973, letter, outlined for HEW "some of the background and philosophy of our role in the delivery of medical care" to help it in its deliberations. VA hospitals were charged by law with serving eligible veterans, and could not admit nonveterans except in bona fide emergencies. Since 1966, however, authority existed for "sharing" the resources of VAH with private hospitals, especially "for the mutual use . . . of

¹Memorandum from Director, Medical Service (Veterans Administration), to Chief Medical Director, "Current VA Hemodialysis Statistics," March 28, 1973.

specialized medical resources in a VA facility which have been justified on the basis of veterans' care, but which are not utilized by the VA to their maximum effective capacity." (Emphasis added.) When a nonveteran was treated in a VA facility under such a sharing arrangement, the VAH provided the services to the other institution, not the individual, billed the other hospital for services, and was reimbursed by it. When a veteran was treated in a non-VA facility under a sharing arrangement, Corcoran wrote, "we consider that element of such institution which is providing needed services as a VA facility." Using this same logic, he continued,

When we provide a service to a patient of a non-VA hospital under a sharing arrangement, we believe we might for the purposes of your law be considered an extension of the hospital that has primary responsibility for the patient's care. In short, we are of the view that the sharing agreement between the hospitals has the effect of making one institution an extension of the other for purposes of providing those medical services purchases within the framework of the sharing agreement.1

This interpretation, in other words, if accepted by HEW, could permit Medicare to reimburse the VA for medical services to nonveteran, Medicare beneficiaries treated in VA hospitals.

The response to Corcoran came from the acting assistant general counsel of HEW for the Social Security Administration. Three "legally possible solutions" to the problem were under consideration. First, under the "community institution" approach, a VA hospital could be considered a Medicare "provider" hospital for specialized services, like dialysis and transplantation, made available to nonveterans under a sharing arrangement with a provider hospital. Payment would be by

¹Letter from John J. Corcoran, General Counsel, Veterans Administration to Wilmot R. Hastings, General Counsel, Department of Health, Education, and Welfare, Washington, D.C., March 29, 1973.

²Letter from Gerald G. Altman, Jr., Acting Assistant General Counsel, Department of Health, Education, and Welfare to John J. Corcoran, General Counsel, Veterans Administration, Washington, D.C., August 3, 1973.

transfer of funds, effected in appropriation bill language. This approach would "possibly require" an agreement between the HEW Secretary and VA Administrator in addition to the arrangement between the VA hospital and the Medicare provider hospital. It was preferred by BHI. A second possibility under Medicare statutory authority would be reimbursement of "such other diagnostic or therapeutic items or services" provided by a VA hospital "under arrangement" with a Medicare provider hospital. The chief drawback of this method was that room, board, or other services falling outside the scope of the quoted provision could not be reimbursed. Finally, the VA-preferred "extension of the provider hospital" concept was also being considered. Though no statute or regulation was known to permit or prohibit this approach, its use "would require some very careful guidelines so Medicare would not be placed in the position of being compelled by precedent to extend this concept to other present nonproviders."

The VA was under pressure to secure an acceptable relationship with Medicare from several divergent sources. It wished to maintain without disruption its long-standing relationships with academic medical centers and physicians, like Kleit in Indianapolis, for whom the "extension" approach was satisfactory but not necessary. The VA also wished to respond to pressures from the Office of Management and Budget and the General Accounting Office to utilize its specialized medical services in an efficient manner. The "extension" concept was suitable for this purpose, and the "arrangement" provision was also acceptable. But it was extremely important to the VA to satisfy its primary clientele, the veterans community. So the Medicare-preferred "community institution" approach, which carried with it the requirement that VA hospitals subject themselves to Medicare regulations on

The GAO was then investigating the VA's specialized medical services; see Comptroller General of the United States, Better Planning and Management Needed by the Veterans Administration to Improve Use of Specialized Medical Services, B-133044, Washington, D.C., June 19, 1974.

providers, was believed to be unacceptable to the watchful veterans organizations and their associated Congressional allies. The approach least preferred by the VA, therefore, was most preferred by BHI and vice versa.

BHI had a somewhat different set of concerns. While acknowledging the problem of the duplication of medical facilities and resources, BHI worried more about the policy issues. It wished to insure that legal bases for cooperation existed and that the chosen arrangement would be "a consistent part of the overall health care delivery system of the Medicare program." BHI wished to establish a comprehensive ESRD system, including minimum utilization rates and medical review under the authority of the HEW Secretary and in a manner that did not relinquish authority to the VA. Furthermore, it wished to avoid setting precedents for other VA medical services and especially wished to avoid foreclosure of any important options for a future national health insurance system.

Discussions between the VA and BHI continued throughout 1973, resulting in increasing clarification of issues but practically no movement toward their resolution. The VA sought and found allies within the disappearing KDCP/RMPS and the emerging ESRD unit within BQA. For instance, Kidder wrote in September: "The RMPS has espoused coordinated employment of ESRD care facilities on a regional basis for the past four years to prevent duplication of expensive facilities and uneconomic increases in professional personnel training, and to improve the quality of ESRD care by establishing centers of excellence at which high cost resources are economically applied in delivering ESRD therapy." This approach, he noted, had been augmented by VA sharing arrangements with non-VA hospitals. The VA, moreover, accounted for an estimated 75-85 percent of all ESRD

Draft Memorandum from Sam Kidder to Acting Director, Division of Medicare Care Standards, "VA Hospital Support to Medicare Providers--VA Desire to be Included in Medicare Delivery of ESRD Therapy," September 27, 1973.

treatment capacity through direct ownership and sharing agreements. I "We believe," Kidder concluded, "that the issue of VA participation under Section 299I provisions should be speedily resolved in favor of VA inclusion." However, he failed to address the issue of whether the VA was to proceed entirely under its own rules or under the rules applicable to the rest of the ESRD system.

Discussion escalated toward the end of 1973 when, on November 13, the VA Administrator, Donald Johnson, wrote HEW Secretary Weinberger. He raised the general issue of Medicare reimbursement for services to nonveterans treated in a VA hospital under a sharing arrangement with a non-VA hospital, and the specific problem of dialysis and transplantation. Johnson reiterated the VA's belief that it could provide renal services to Medicare beneficiaries in a VA facility under sharing agreements, and repeated the preference for doing so under the "extension" concept. He further noted that the Medicare ESRD cashflow problem had left one private hospital in substantial arrears in paying the VA hospital treating its patients on a sharing basis. "The private hospital is unable to recover from the patient," he wrote, "and is unable to divert funds from other sources to make this payment and, obviously, the VA cannot continue to treat patients indefinitely under a sharing agreement without reimbursement." Weinberger responded on January 3, 1974, expressing sympathy with the desire to avoid duplication, noting "statutory and administrative difficulties," and pledging continued cooperation "in developing a mutually agreeable approach consistent with statutory authority." He also promised a "summary of the outstanding issues and questions."

On March 8, 1974, the VA Administrator, in a letter to the HEW Secretary, acknowledged receipt of materials that seemed to him "a compilation of various documents about Medicare reimbursement. The materials did emphasize, Johnson wrote, "the need to have some basic

¹No documentation supporting this claim was provided.

²Letter from Donald E. Johnson, Administrator, Veterans Administration, to Caspar W. Weinberger, Secretary, Health, Education, and Welfare, Washington, D.C., March 8, 1974.

policy decisions made," and he asked Weinberger for "a high level meeting" to discuss policy and legal issues with the respective general counsels represented. Recent inquiries, he noted, had come from OMB, the Senate Committee on Veterans' Affairs, and the Renal Physicians Association indicating growing political interest in the matter. He again repeated the VA preference for the "extension" concept.

Weinberger responded to Johnson in mid-April, agreeing to the requested meeting and then identifying two issues having "major policy consequences" that required "special attention." The first was how VA facilities were to be involved in "the development by this Department of a unified and coordinated renal disease treatment system for the United States," which would be implemented under regulations issued by the HEW Secretary. The second issue was finding "a mechanism consistent with both our statutes whereby funds may be channelled appropriately and in appropriate amounts."

Before H.R. 1, Cardwell's report stated, service provided to Medicare beneficiaries by federal hospitals, including VA hospitals, were generally excluded from coverage, unless the Secretary found such hospitals to be serving the general public as "community institutions." A VA hospital could not be designated a community institution for providing a limited service to a select group of Medicare patients transferred to it from a Medicare-participating hospital; all its services had to be available to the general public. "The exclusion," the report said, "was intended to assure that Medicare would not become the basis for financing a federally operated health

Letter from Caspar W. Weinberger, Secretary, Health, Education, and Welfare, to Donald E. Johnson, Administrator, Veterans Administration, April 15, 1974; and James B. Cardwell, Commissioner of Social Security, "Report to Secretary Caspar W. Weinberger regarding status of HEW-VA deliberations on potential coordination of renal treatment programs."

²Cardwell suggested that Weinberger raise these issues to counter the impression in Johnson's March 8 letter that "the only outstanding issues are administrative technicalities."

care service to treat Medicare patients," a policy strongly supported by Congress, organized medicine, and nonfederal hospitals.

Although P.L. 92-603 extended Medicare benefits to nearly all victims of chronic renal disease regardless of age, it did not alter the coverage of services. Existing law limited coverage of services provided by VA hospitals to in-patients of participating hospitals to diagnostic and therapeutic services, billed through the Medicare participating hospital, excluding items like "room, board, routine medications, nursing services and operating room recovery costs." Moreover, payment was contingent upon the patient remaining under the overall responsibility of the participating hospital. "Outpatient dialysis services furnished to a Medicare beneficiary by a VA hospital under arrangements with a participating hospital, on the other hand, are not reimbursable," the report declared.

The SSA/BHI report reviewed the development by BHI, in conjunction with the Office of the General Counsel, of the three legal possibilities and associated administrative arrangements--community institutions, under arrangement, and extension of provider hospital. In response to the VA expressed preference for the last of these, BHI informally provided them an analysis of the requirements, regulations, and administrative instructions that would have to apply to the relevant VA hospitals. The main question, then, became the specific conditions a VAH renal disease department would have to meet to be considered an extension of another hospital. These conditions would require examination of the legal relationship between the VA and Medicare-participating hospital, accreditation of the VAH would be insufficient because "special conditions" were being established for Medicare renal facilities, and payment would have to be based upon Medicare cost accounting procedures. The "orderly development" of the ESRD program, including VA participation in it, the report concluded "would appear to require coordination of planning, under the leadership of the Office of the Secretary, for rational expansion of VA facilities with other facilities participating in the Medicare program, in accordance with the provisions of Section 299I of P.L. 92-603."

In short, the implications of the Medicare policy against paying for services provided Medicare beneficiaries by federal hospitals, under any of the legally possible arrangements, involved the loss of autonomy by the VA to the HEW Secretary and the administrators of Medicare.

In January 1974, while negotiations between HEW and the VA were under way, Dr. Alvin Goodman assumed responsibility for the BQA ESRD unit. Goodman, a practicing nephrologist, had taken leave during 1974 from Grasslands Hospital in Westchester County, New York. An energetic physician, and clearly not a career civil servant, he had no hesitation about circumventing normal bureaucratic procedure. When the VA matter came to his attention, he viewed it less as a conflict between different views of the public interest and more like "turf-protecting" behavior of two bureaucracies. He went to Jay Constantine and James Mongan, professional staff of the Senate Finance Committee, and they in turn brought in John Steinberg, staff to the Senate Committee on Veterans.

Matters came to a head in late spring 1974. The "high level meeting" requested by Johnson occurred on May 3 at 9:30 a.m., in the office of the HEW General Counsel. Robert Coy, VA General Counsel, and Dr. Paul Haber, VA Deputy Medical Director for Clinical Services, met with Wolkstein and others from BHI, Goodman, and representatives of HEW's general counsel. Motivated by a meeting called for 10:30 a.m. that morning by Constantine and Steinberg, the administrators accepted previously developed basic principles of an interagency agreement. They then adjourned, reconvened on Capitol Hill, and with the two Senate staffers in the chair, worked out more of the details of the agreement.

This pressure on the bureaucracy by the Congressional staff produced an agreement which, as summarized by Coy, rested on the Medicare-preferred "community institution" concept. VA hospitals

¹Memorandum from VA General Counsel to VA Chief Medical Director, "VA-HEW Problem Relating to Reimbursement under Sharing Contracts for Services Provided to Medicare Beneficiaries," May 10, 1974.

treating nonveteran renal patients of non-VA, Medicare provider hospitals under sharing agreements, would themselves be regarded as Medicare providers for reimbursement by the ESRD program. They would have to meet the same HEW standards required of all other providers for ESRD certification, including utilization review conducted internally by VA physicians and external review in which VA would be represented. The VA consented to BHI, according to Coy, because Haber had concluded that "in this one area" of kidney treatment, the VA medical program "could live with" HEW requirements on providers. On general matters, Haber wrote: "The door is left open for comparable action in other sharing agreements but we stressed that they will have to be reviewed individually. I am somewhat guarded about VA's submitting to utilization review in other areas."

Subsequently, the respective agencies prepared a Memorandum of Understanding, signed on September 4, 1974, by Weinberger for HEW and Johnson for the VA regarding services covered for the treatment of end-stage renal disease. The memorandum acknowledged the "scarcity of facilities" for treating renal disease and the role played in this regard by VA hospitals. Twenty VA hospitals with sharing agreements with Medicare participating hospitals were listed as "community institutions" for purposes of Medicare reimbursement for end-stage renal disease.

The policy issue, it appeared, finally had been resolved, nearly two years after the enactment of P.L. 92-603 and 15 months after the effective date of the program. Unaided by Congressional intervention, resolution may have eluded the bureaucracy much longer.

But the Memorandum of Understanding only appeared to resolve the issue. Reluctant to subject themselves to HEW regulations or to cost their services in accord with Medicare accounting principles, the VA engaged in substantial delay in the actual implementation of the

¹Memorandum from VA Deputy Medical Director for Clinical Services to VA Chief Medical Director, "Meeting with HEW, Senate Finance and Veterans' Affairs Committee on Reimbursement under HR-1 for Medicare Beneficiaries Dialyzed by VA Sharing Agreements," May 7, 1974.

agreement. Although interim emergency payments were made beginning in late 1974, it was not until early 1978 that regular Medicare payments to the VA were made! One practical effect of this extended conflict has been the disestablishment of many of the operational aspects of sharing agreements for both dialysis and transplantation.

The HEW-VA renal experience suggests a possible scenario for any expanded national health insurance effort. The issue is unlikely to be addressed in legislation with the probable consequence being that negotiations between HEW and the VA will be required. Policy agreement is apt to come only after lengthy, complicated negotiations, which may require Congressional intervention to complete. It is unlikely that policy will be implemented readily; operational problems will then become the focus of both policy and organizational conflict.

Home Dialysis

The dialysis of end-stage renal disease patients in the home first occurred in Boston in 1964 and soon thereafter in Seattle. It was in Seattle, however, that Dr. Belding H. Scribner of the University of Washington Medical School pioneered the extensive use of home dialysis. Dr. Christopher Blagg, Scribner's associate, reported in 1977, for instance, that in Washington State, home dialysis patients had consistently exceeded 75 percent of the total in the previous eight years, and that Indiana had averaged 60 percent or more for many years. For the Veterans Administration dialysis population, as noted in the previous section, over 45 percent was either receiving home dialysis or home training in early 1973. At the national level, the home dialysis proportion of total dialysis patients was 40 percent on January 1, 1972, and 36 percent a year later. 2

¹C. R. Blagg, "Incidence and Prevalence of Home Dialysis," Journal of Dialysis, Vol. 1, No. 5, 1977, p. 480.

²F. A. Bryan, Jr., The National Dialysis Registry: Development of a Medical Registry of Patients on Chronic Dialysis, Final Report: June 1967-August 1976, Research Triangle Institute, Research Triangle Park, North Carolina, August 1976, pp. 10, 11.

One reason for the attractiveness of home dialysis to many policy officials is that mortality data over time and across many countries reveal that home patients generally do better than center patients. Another attractive feature of home dialysis to many is that it is the least costly means of dialysis treatment.

It was with some distress, therefore, that a number of physicians realized soon after publication of the interim regulations that the Medicare program had created a number of disincentives to home dialysis. Distress deepened into sustained disappointment as the proportion of dialysis patients in the home setting dropped steadily to less than 15 percent in 1978. How this situation developed as a result of inadvertent policy decisions by the government is set forth in this section.

In fall 1973, nine physicians analyzed the obstacles to home dialysis created by the interim regulations in five problem areas: equipment, operational costs, physician fees, costs of a dialysis helper other than the patient's spouse, and the entitlement waiting period. For fixed equipment, home dialysis patients were required to pay the 20 percent Medicare co-payment at the outset and then accept a monthly lease arrangement for the remaining 80 percent; and no provision was made for equipment maintenance. Under operational

¹See P. V. Stange and A. T. Sumner, "Predicting Treatment Costs and Life Expectancy for End-Stage Renal Disease," New England Journal of Medicine, Vol. 298, February 16, 1978, pp. 372-378; and H. J. Gurland et al., "Combined Report on Regular Dialysis and Transplantation in Europe, VI, 1975," pp. 17, 18, in B.H.B. Robinson et al. (eds.), Dialysis Transplantation Nephrology: Proceedings of the Thirteenth Congress of the European Dialysis and Transplant Association, 1976, The Pittman Press, Bath, 1976.

²See Stange and Sumner, op. cit., and Blagg, op. cit.

³J. Bower, C. R. Blagg, J. Eschbach, D. Hathaway, D. Ogden, E. Rutsky, T. K. Sawyer, B. H. Scribner, and A. M. Siemsen, "Obstacles Which Impeded the Implementation of Home Dialysis Under H.R. 1," n.d. (but September 1973).

⁴Full payment equals the 80 percent of allowable charges reimbursed by Medicare and the 20 percent co-payment requirement to the patient.

costs, it was noted that home patients were more likely than center patients to have to pay the 20 percent co-payment for supplies: suppliers billed home patients directly and were normally unwilling to make the next supply delivery without full payment; center dialysis patients, by contrast, did not deal with suppliers, but only with facilities providing treatment; facilities, in turn, often absorbed the supply co-payment requirement in their own expenses, rather than pass it on to the patient. Moreover, some supplies covered in center dialysis were not covered under use in the home setting. Physician fee arrangements were especially adverse to home dialysis: where center physicians could receive a portion of the facility "overhead" for general patient supervision, no matter how distasteful the arrangement, physicians with home patients were deprived of even this compensation. Only if a home patient became ill, was hospitalized, or had a routine checkup could physicians supervising home dialysis patients be paid for their services. And no physician fee was provided for home dialysis training. Home dialysis helpers, moreover, could not be reimbursed, though reimbursement of highly trained nursing and technical personnel occurred in centers. Finally, the three-month waiting period for patients to become eligible to receive ESRD benefits meant that home dialysis training, if it was to be reimbursed, could not be initiated until after the waiting period was over.

The recommendations made by these physicians included 100 percent reimbursement of initial equipment, home supplies, and all services covered by Part B. Some means for reimbursing physicians for general supervision of the home patient was recommended, as was a flat physician's fee for home training. Also recommended was reimbursing home helpers, shortening the waiting time to permit home training to begin early, and increasing the home training fee paid to the training center.

The primary source of equipment problems lay in the Medicare policy for "durable medical equipment," the provision of the

Durable medical equipment is defined by Medicare as equipment that meets all the following requirements: (1) it can be used

regulations governing the reimbursement of dialysis equipment and supplies used in the home. Medicare almost exclusively favored lease arrangements, while the equipment industry and medical community experience before P.L. 92-603 was based on purchase of equipment. Medicare's lease orientation had nothing to do with the economic implications of lease versus purchase for the ESRD program, nor with the incentives to and burdens on the home dialysis patient. Patients could either rent or purchase a machine, but purchase required full payment to the supplier, of which 80 percent was reimbursed by Medicare; 24 equal monthly installments were to be paid over two years. This policy remained unchanged until it was altered in 1978 by legislation.

The ESRD program instituted temporary special procedures for reimbursing home dialysis supply claims in fall 1973, as part of the special procedures then being adopted for the entire program. The program emphasized to fiscal carriers and regional offices that any delay in claims processing could cause "significant financial hardship" for home dialysis patients.

The BHI also sought to eliminate the inequity between home and center patients on covered supplies. It identified syringes, alcohol wipes, adhesive tape, bandages, alcohol, beadine, and underpads as those "generally uncovered items" for home dialysis patients which, nevertheless, were reimbursed for treatment in centers. Covered supplies include dialyzers, venous and arterial sets, dialysate, saline solutions, administration sets, fistula needles, and Heparin. The distinction was between those items required for "the effective operation of a home dialysis machine," and those that were not. The following solution was found: ". . . if such non-covered items are included in a package with covered items, the reasonable charge for Medicare reimbursement purposes will be the

repeatedly, (2) it is primarily and customarily used for a medical purpose, (3) it generally is not useful to a person in the absence of an illness or injury, and (4) it is appropriate for use in the home.

lesser of the total of individual reasonable charges for all covered items in the package when purchased separately in comparable quantities, or the package charge." In short, inclusion in a "package" permitted reimbursement.

Another problem that was not initially identified by the physicians arose in the first year: Medicare would reimburse for home dialysis equipment to patients only during period of use, but not for temporary nonuse. Temporary nonuse could occur, for instance, when the beneficiary required in-patient treatment for restabilization or some acute medical problem, was temporarily without the assistance of a spouse or family member, was away from home but expected to return, or was awaiting a transplant operation. In March 1974, BHI revised its guidelines to permit continued reimbursement for home equipment for up to three months after the last use. This same I.L. eased the cash-flow problems of suppliers, which were now being paid on monthly rather than a lump-sum basis, by allowing those suppliers to add interest and carrying charges to allowable charges. Installation and delivery charges for home dialysis equipment were also allowed by this instruction.

A resolution of the physician fee problem awaited the Secretary's final policies of April 1974 and the accompanying I.L. of June. The "final policies" briefly noted that "since it is primarily a physician decision as to the mode and setting of therapy for the patient . . ., any incentive to the physician to preclude self-dialysis and home dialysis should be corrected." Henceforth, physicians supervising home patients would also be entitled to a comprehensive monthly retainer fee. Furthermore, a flat fee for physician services for home dialysis training was to be established.

¹I.L. 73-35(B), "Processing Claims for Home Dialysis Supplies for Chronic Renal Disease Beneficiaries," October 1973.

²I.L. 74-10(A)/74-8(B), "Durable Medical Equipment Used for Home Dialysis," March 1974.

³Department of Health, Education, and Welfare, "Final Policies: P.L. 92-603, Section 299I, End-Stage Renal Disease Program of Medicare," April 1974.

It remained for the I.L. to define the details. The monthly retainer for physicians supervising home patients had the same range of charges of not less than \$8 nor more than \$12 as dialysis center physicians choosing the alternate method, but included a "conversion factor" multiplier of 14 rather than 20, and ranged from \$112-\$168. The lower conversion factor was justified because "self-dialysis patients usually do not receive or require as extensive services as patients in facilities who are not on self-dialysis." Physicians supervising self-dialysis or home dialysis training were to receive a flat fee of \$500.

Thus, one year after the program became operational, HEW had taken steps to remove some of the disincentives to home dialysis. But because some other disincentives derived from the Medicare statute, legislation was necessary to address them.

Concerned physicians focused their attention on the Senate
Finance Committee, where the professional staff, Jay Constantine and
James Mongan, were sympathetic listeners. The Renal Physicians
Association president, Dr. John H. Sadler, wrote Senator Russell Long
on December 13, 1974, urging changes in legislation to encourage home
dialysis. Specifically, RPA proposed the following: entitlement at
the time home training begins; 100 percent coverage of equipment and
supplies, including those supplies needed to use the equipment; and
permission for direct purchase, lease, or rental of home equipment
based on economic considerations.

These discussions resulted in the introduction by Long of S. 1492 on April 21, 1975, a bill "to provide incentives and otherwise to encourage the utilization of home-dialysis and to encourage early kidney transplantation." The bill proposed that entitlement begin in the month when a patient began an approved self-dialysis training program; it also proposed that entitlement continue for 36 months after receipt of a transplant, rather than 12 months as

¹I.L. 74-20(A)(B), "Alternative Reimbursement Method of Monthly Payments to Physicians for Services Rendered to Patients on Maintenance Dialysis," June 1974.

required under existing law. For individuals in approved self-dialysis training programs or "self-dialyzing at home or in an approved self-dialysis facility," the proposed language called for:

payment with respect to medically necessary items, services, or supplies in connection with self-dialysis (including physician's services . . .) covered under part A or part B of Title XVIII shall be made for 100 percentum of the reasonable cost or reasonable charge for such . . .; and the provisions of such part A or part B relating to deductibles and coinsurance shall not apply to such items, services, or supplies. . .1

No hearings were held on this bill and no further action was forthcoming in the Senate.

In the House, however, 1975 was the year in which Representative Wilbur Mills (D., Ark.) relinquished the chairmanship of the Ways and Means Committee. Under the new chairman, Rep. Al Ullman (D., Ore.), subcommittees were established for the first time. Rep. Charles A. Vanik (D., Ohio), chairman of the Subcommittee on Oversight, began an inquiry into the ESRD program that produced a background document, a set of hearings, and a subcommittee report. Much subcommittee attention focused on how to arrest the declining proportion of home dialysis patients, and Vanik introduced a bill on February 19, 1976, to help accomplish this. The H.R. 12012 was longer, more comprehensive, and different from Senator Long's bill. Entitlement would begin in the first month of dialysis for a person beginning home training. The

¹S. 1492, April 21, 1975, 94th Cong., 1st sess.

²U.S. House of Representatives, Committee on Ways and Means: Background Information on Kidney Disease Benefits Under Medicare, Committee Print, 94th Cong., 1st sess., June 29, 1975; Medicare's Kidney Disease Benefits Program, Hearings, June 24 and July 30, 1975; and Reports on the Administration by the Social Security Administration of the End-Stage Renal Disease Program Established by Public Law 92-603 (with additional views) and on the Social Security Medicare Research Studies, Committee Print, October 22, 1975.

deductible and co-payment provisions of Part B would be retained in the reimbursement of home dialysis equipment and supplies, but all such expenses were now to be covered. The bill called for the Secretary to survey designated areas of the country to determine the accessibility of home dialysis training facilities. He was then to develop a program to insure that such training was accessible and that "at least 50 percent of all individuals in the area . . . suffering from end-stage renal disease and requiring renal dialysis will actually be undergoing home dialysis or receiving home dialysis training." Other provisions of the bill addressed pilot projects, experiments, and studies that would aid the government in determining the appropriate policy for home dialysis.

No further legislative action occurred in the 94th Congress, but the ground work had been done for the 95th Congress that convened in 1977. On February 3, 1977, Rep. Dan Rostenkowski (D., Ill.), Chairman of the Health Subcommittee of the Committee on Ways and Means, together with Rep. Vanik, introduced H.R. 3112. Like Vanik's previous bill, early entitlement was proposed for those beginning self-dialysis training. The new bill extended the provision in the earlier bill that 50 percent of renal patients be on home dialysis or training for it. First, renal disease networks were proposed, which would have medical review boards; these boards, among other functions, were to encourage "the use of self-care dialysis settings." The Secretary, then, on the basis of data from those networks, was to establish the appropriate proportion for self-dialysis and self-dialysis training for each network on the basis of the following:

With respect to all networks, such proportion shall be equal to 40 percentum by October 1, 1978, 50 percentum by October 1, 1980, and such additional percentum . . . thereafter as the Secretary, in consultation with the medical review board, shall determine.

¹The network language merely incorporated into the bill the previous policy established by regulations. The development of networks is analyzed in the following section.

What was not being done by physicians and patients and could not be done by administrative action was proposed to be accomplished by legislative fiat.

At a one-day hearing on April 25, most witnesses supported the general effort to eliminate financial disincentives to home dialysis. But no one supported the establishment of quotas. HEW, the RPA, the NKF, the National Association of Patients on Hemodialysis and Transplantation, National Medical Care, Inc., and others all opposed the stipulated quotas.

A "clean" bill, H.R. 8423, reported by the subcommittee to the full committee, introduced some important modifications. Facilities could now be reimbursed for providing home dialysis supplies to home patients. Reimbursement for 100 percent of equipment costs was also authorized for home patients where equipment was purchased by facilities responsible for patient management. Reimbursement for home dialysis was to be based on a target rate, not to exceed 70 percent of the national average rate, adjusted for regional variations, for facility-based maintenance dialysis. Quotas were eliminated, but the language stated: "The national objective with respect to the appropriate proportion of patients in self-dialysis settings and preparing for or undertaking transplantation is that a majority of new patients being accepted for end-stage renal disease treatment should be in self-dialysis settings or be transplanted." The House of Representatives, adopting the measure under a "suspension of the rules" procedure on September 12, 1977, appeared determined to wrest economies from the ESRD program.

Events took a different turn in the Senate. There, H.R. 8423 was introduced by Sen. Long and was the subject of a hearing on October 21, 1977. The health subcommittee of the Senate Finance

¹U.S. House of Representatives, Committee on Ways and Means, *Medicare End-Stage Renal Disease Program Amendments*, Hearing, 95th Cong., 1st sess., April 25, 1977.

²U.S. Senate, Committee on Finance, Hospital Cost Containment and End-Stage Renal Disease Program, Hearings, 95th Cong., 1st sess., October 12, 13, and 21, 1977.

Committee and the Committee staff, chaired by Sen. Herman Talmadge (D., Ga.) with Sen. Robert Dole (R., Kan.) as ranking minority member, was disposed to enact the House bill with relatively few changes. Representatives of the RPA and the NKF basically supported the bill. Dr. Arvin Weinstein, president of the NKF, for instance, testified that "We are much more comfortable with the articulation of national goals rather than what was in an earlier version of a bill; that is, fixed quotas for self-dialysis." He concluded by saying, "we endorse virtually all of the important provisions of the bill."

The gentlemen's agreement to support H.R. 8423 was shattered by National Medical Care. National Medical Care, Inc. (NMC), a Bostonbased corporation founded in 1968 and publicly owned since 1970, provides maintenance dialysis in nonhospital limited-care centers throughout the United States. It has prospered under the ESRD program, partly because the facility reimbursement screen has forced out-patient maintenance dialysis outside hospital-based facilities into less expensive settings and partly because of the disincentives to home dialysis. Its president, Dr. Eugene Schupak, testified before the Ways and Means Committee in April. Preceding him, however, was Dr. Belding H. Scribner, from the University of Washington, Seattle, who charged: "What started out in 1960 as a noble experiment gradually has degenerated into a highly controversial billiondollar program riddled with cost overruns and enormous profiteering." Noting the decreased proportion of home patients, Scribner attributed the decline to the disincentives in the regulations and to the fact that "the present regulations have encouraged the rapid expansion of a very profitable business, selling in-center dialysis to the Government." He reiterated the profiteering charge later that fall on the nationally telecast program, "60 Minutes."

There exists a long-standing Boston-Seattle rivalry, if not enmity, on issues of end-stage renal disease. NMC had prepared its

¹⁶⁰ Minutes, Vol. X, No. 8, as broadcast over CBS Television Network, Sunday, October 30, 1977, "What Price Medicine?"

response for the Senate hearing in October. Dr. Edmund Lowrie of Peter Bent Brigham Hospital in Boston attacked the Seattle experience directly on two points: "Our analysis indicates that the cost of self-care dialysis is not significantly less than limited care dialysis, and that the indiscriminate use of home dialysis may lead to unacceptable patient mortality." Although he buttressed his cost argument with a comparison of Boston and Seattle costs, seeking to show that the latter could not do home dialysis as cheaply as they claimed and that the cost differential between home and limited-care dialysis was slight, no one took the point seriously: the bill, after all, would limit home dialysis reimbursement to 70 percent of facility maintenance dialysis or less. The mortality argument was more effective.

Lowrie cited material submitted by Blagg, director of the Northwest Kidney Center, to Vanik's subcommittee in 1975, indicating that 58 percent of patients survived three years in a program that trained 80 percent of its patients for home dialysis. That, he noted, was less than the national average, and well below most major centers. "After careful analysis," Lowrie claimed, "the only obvious reason for this inferior patient survival that we can think of is the indiscriminate use of home dialysis therapy." Lowrie's testimony created the impression that three-year survival of home patients in Seattle was unacceptably low. Blagg later pointed out that the 58 percent applied to all Seattle patients, center and home, and included elderly and diabetics in significant numbers. "When we look at patient survival on home dialysis," Blagg wrote, "and exclude the center dialysis patients, the three-year survival [rate] in our program is 74 percent including diabetics; if we exclude diabetics, the three-year survival rate in patients aged 55 or less is 81 percent on home dialysis, and for patients over the age of 55 is 55 percent. These results are comparable to other programs."

Lowrie cited his affiliations with Harvard Medical School, Peter Bent Brigham Hospital, and Massachusetts Institute of Technology, but not with the Kidney Center of Boston, an NMC-affiliate, to which he referred patients for maintenance treatment and which he directs today.

But the political damage had been done. Senator Dole asked the General Accounting Office (GAO) to update its 1975 report relative to the mortality and costs of home versus center dialysis. GAO reported that National Dialysis Registry data for 1972 to 1974 showed survival slightly higher for home patients than center patients. Dole issued a press release expressing his concern for not wanting to encourage a "form of treatment that might prove to be a risk to patients," noting cryptically that the GAO report "addressed many of his concerns."

The legislative process was arrested. No further action occurred until early February 1978, when the Senate Committee mark-up of H.R. 8423 occurred and a bill was reported to the Senate on March 22, 1978. Eliminated was any reference to national goals for home dialysis and transplantation. The Senate adopted the revised bill on April 10.

Lengthy negotiations followed between the staff of the two committees, several complicated parliamentary maneuvers occurred, and finally agreement on a bill was reached. Public Law 95-292, signed on June 13, 1978, retained the early entitlement for self-dialysis training, provided that facilities could be reimbursed for furnishing home patients with equipment and supplies, included 100 percent reimbursement for home dialysis equipment if managed by a facility, and limited the reimbursement of home dialysis to 70 percent of facility reimbursement. The stated intent of Congress was that "the maximum practical number of patients who are medically, socially, and psychologically suitable candidates for home dialysis or transplantation should be so treated." This was a far cry from where the House began.

All the ways in which ESRD reimbursement procedures introduced disincentives to home dialysis and incentives to center dialysis for both patients and physicians were identified soon after the program became operational. Some disincentives were eliminated by the exercise of administrative discretion in the program's initial year, but others required legislative action. The legislative process, however, was (and is) long, uncertain, and highly political. The effects of

Newsletter from U.S. Senator Bob Dole, "G.A.O. Study on Dialysis Released," Press release, November 7, 1977.

P.L. 95-292 on increasing the proportion of home dialysis patients remain to be seen, but they are likely to be modest.

Why should decisionmakers have such difficulty expressing a clear policy preference for the dialysis treatment that has the least cost, when survival data show it to be as good, if not better, than institutional dialysis? Several characteristics of patients and of physicians interact in the decision to undertake home dialysis, which strongly affect the willingness of administrators and Congressmen to formulate policy for home dialysis. Patients must reside in physical structures capable of being modified to accept an artificial kidney machine and the associated equipment and furnishings. They must also be suitable candidates for home dialysis, in clinical, psychological, and social terms. In choosing home dialysis, though, patient behavior is affected by financial considerations, personal disposition toward independence rather than dependence, spouse and family orientation to help, and the influence of the physician in their decision. Physicians must determine the suitability of the patient for home dialysis, but as a group they exhibit wide and strong differences of opinion on all dimensions of suitability, including clinical suitability. Physicians influence, if not determine, patient decisionmaking to a large extent, so they must themselves see home dialysis as desirable for the patient and then help the patient to see it in the same light. Finally, physicians make their judgments, in part, on the basis of their personal financial interest in home versus institutional dialysis.

The consistently high proportion of dialysis patients in the home setting found in some regions of the United States suggests that the clinical upper limit may be relatively high for the nation as a whole—even with age, race, and other factors taken into account. But difference of opinion within the patient population and the

In contrast to the United States, the United Kingdom, Australia, and New Zealand, respectively, were treating 66.5, 49, and 46 percent of dialysis patients at home as of December 31, 1976 (United Kingdom) and October 31, 1978 (Australia and New Zealand). See C. Jacobs et al., "Combined Report on Regular Dialysis and Transplantation in Europe, VII, 1976," pp. 16-17, in B.H.B. Robinson, ed., Dialysis Transplantation Nephrology, Proceedings of the Fourteenth Congress of the

physician community creates a situation in which administrators and Congressmen have no defensible position from which a stronger home dialysis policy might be defended. Policies are difficult, if not impossible, to make that constrain patient freedom of choice and favor one clinical view over another.

Cost Containment

HEW regarded the screen on facility reimbursement of outpatient maintenance dialysis as its primary instrument of cost containment. Although the \$150 amount was deemed reasonable, given the wide variation in charges across the country, it was never viewed as permanent. Expectations were that the program would acquire cost data over time, on the basis of which the screen would be recalculated. Before this assumption could become the basis for action, however, the government had to withstand a legal challenge to the authority of the Secretary to reimburse nonprovider facilities in the manner specified in I.L. 73-25(A)/73-22(B), and a subsequent challenge to his authority to collect cost data from such facilities.

The basis for the reimbursement of nonhospital, dialysis facilities was to be the weighted average of all dialysis services reimbursements from all third parties made to the facility during the previous 12 months, subject to the limit of \$150 per treatment. The Medicare intermediaries were to determine the specific reimbursement rate for each facility by examining charge data for the previous year in light of the formula. Many intermediaries, however, did not bother to do so but simply set the initial level at the \$150 limit. In one notable case, however, that situation did not occur, with results which affected the government's ability to revise the screen in light of program experience.

European Dialysis and Transplant Association, held in Helsinki, Finland, 1977, Bath, The Pitman Press, 1977; and see Second Report of the Australia and New Zealand Combined Dialysis and Transplant Registry, sponsored by the Australian Kidney Foundation, Canberra City, Australia, May 1979, pp. 10-11.

The Queens Artificial Kidney Center, Jackson Heights, New York, had treated Medicare patients since it was established in 1970, and had billed for its services through Group Health, Inc., New York, the Medicare carrier. Nonprovider billing under the ESRD program, however, was to be through intermediaries, not carriers, and a limited-care facility was to bill through the intermediary that served the hospital with which it had its primary affiliation. In the case of Queens, its affiliation was with the Mount Sinai School of Medicine. But the latter was one of a small number of institutions which, by choice, had elected to bill Medicare not through the New York intermediary but through the Division of Direct Reimbursement, BHI, a government intermediary. The government intermediary, perhaps more conscientious in meeting its renal responsibilities, scrutinized the Queens situation carefully.

During the 12-month period from July 1, 1972 through June 30, 1973, the Queens facility had been reimbursed at \$75 per treatment by New York State Medicaid. It had been reimbursed for Medicare patients by Group Health, Inc., during this same period at \$150 per treatment. Because the ESRD program, which began on July 1, 1973, was administered by Medicare, Dr. Eugene I. Schupak, proprietor and director of the Queens facility, assumed that the \$150 per treatment rate would prevail. But because the New York Medicaid patients accounted for 61 percent of the facility's patients, when the weighted average formula was applied the Medicare allowable charge was only \$99.09.1

Schupak felt unfairly treated. The State Medicaid payment, for instance, had been \$90 per treatment for two months in early 1970 and \$100 per treatment from May 1970 to September 1, 1971. Thereafter, the low rate of \$75 had applied, but an upward adjustment to \$90.62 per treatment had been made on July 1, 1973. So the weighted average formula was applied to the Queens facility at the low point of its reimbursement by New York Medicaid.

 $^{^{1}}$ Medicare reimburses 80 percent of the allowable charge.

Schupak entered into lengthy negotiations with BHI, one result of which was the upward adjustment of the Medicare allowable rate to \$107.16 per treatment. This was unsatisfactory to him because his facility and only three others in New York City were being reimbursed at less than the full limit. BHI invited Schupak to submit cost data demonstrating a hardship and, if these were persuasive, an appropriate adjustment would be made. He refused to do so.

The reasons for the refusal lie in an ESRD program effort then under way to collect cost data on out-patient dialysis, in the corporate nature of the Queens facility, and in the perceived risks to Queens of providing such data.

In December 1973, BHI distributed a Renal Dialysis Questionnaire to provider and nonprovider facilities to secure data that would permit intermediaries to evaluate a facility's charge or cost per dialysis, and Medicare to evaluate reimbursement issues. A follow-up I.L. in November 1974 noted that about half of the 600 dialysis facilities had not returned the questionnaire, stressed the importance of compliance, and asked for documentation of inability to respond. Nonrespondents included many limited-care dialysis facilities, both nonprofit and proprietary.

Schupak's facility was among the proprietary nonrespondents. In fact, the director of the Queens facility was also president of National Medical Care, Inc., the nation's largest provider of limited-care dialysis services, all under proprietary auspices. 4 None of the

Subsequent to the establishment of the alternative method of physician reimbursement, the screen for facility reimbursement was adjusted downward to \$138 for those facilities where physicians elected the alternate method.

²I.L. 73-53(A), "Questionnaire--Renal Dialysis Reimbursement," December 1973.

³I.L. 74-32(A), "Follow-up on Renal Dialysis Questionnaire Not Yet Received," November 1974.

⁴Schupak was the sole proprietor of the Queens Artificial Kidney Center, and leased the facility and equipment from National Medical Care, an arrangement that differed from most NMC facilities, which were wholly owned by the Boston corporation.

NMC affiliated dialysis centers had returned the ESRD questionnaires or had in any other way provided BHI with cost data. They reasoned that their data would present an opportunity to the government to reduce charges in facilities which showed a profit; that they would be shared with others, including competitors; and that the government had no right to such data.

On July 11, 1975, Schupak filed suit against David Mathews, Secretary of Health, Education, and Welfare, in the U.S. District Court for the District of Columbia. Schupak argued, essentially, that the reimbursement rate established by the interim regulations and I.L., first, had been improperly issued in violation of the Administrative Procedures Act (APA) and, second, that it also violated the Medicare Act's requirement that reimbursement be based on reasonable charges; he asked the Court for summary judgment. The government responded that the plaintiff had not exhausted administrative remedies, that the court lacked jurisdiction in the matter, that the regulations and I.L. were not issued in violation of APA, and that the substance of the reimbursement rate represented a reasonable exercise of discretion by the Secretary in the instance; it asked the court to dismiss the plaintiff's motion and give a summary judgment.

Judge William B. Bryant, in his opinion, held that the plaintiff had exhausted all administrative remedies, that the court did have jurisdiction, and that the government had not complied with the requirements of the APA. Specifically, on this last point, the court pointed out that the I.L

. . . contains that specific [reimbursement rate] formula itself. It directly controls the reimbursement to be paid

¹Schupak v. Mathews, No. 75-1109 (D.D.C., filed July 11, 1975).

²A summary judgment is warranted when the material facts are not in dispute, a trial is therefore unnecessary, and the judge need only rule on the law relative to the facts.

³If Schupak had prevailed, BHI calculated that it might be liable for as much as \$2-3 million in retroactive reimbursements due to Queens for the three years beginning July 1, 1973. Thomas Tierney, director of BHI, decided the government should respond to the litigation because of the cost implications. "If I am going to have to pay out \$3 million, I want to be told to do so by the Court."

to dialysis facilities, and has a substantial impact on the rights of those facilities. It is definitive, new, and controlling, and is precisely the sort of regulation required to be imposed only pursuant to the rulemaking requirements of the APA. Accordingly, the Court holds that such a rule may only be promulgated pursuant to these procedures, including the public participation and notice provisions of the APA. 1

Bryant then ordered that the I.L. be "set aside as void and of no effect," but that the order be stayed until a regulation replacing the I.L. could be promulgated in accordance with the APA requirements.

The substance of the dispute was whether the Secretary had acted within his authority in establishing the criteria for determining "reasonable charges" published in the interim regulations and, specifically, whether the estimated customary charge formula of the I.L. provided a basis for legally reimbursing reasonable charges in general and for the plaintiff. In Bryant's judgment:

Given the Secretary's responsibilities under the new program, the complexity and novelty of the issues it raised, and the discretion in determination of reasonable charges delegated to him by Congress in this matter, the Court finds the regulation and formula adopted to be legal and reasonable.

The judge further upheld the government on all questions of substance, and the plaintiff's arguments were rejected as without merit.

The District Court judgment was filed on September 17, 1976. In response, HEW published a Notice of Proposed Rulemaking on November 9, 1976, which, among other things, included a republication of the interim regulations, clarification of the criteria for reasonable charge determinations for nonprovider dialysis facilities, and specifications of the requirement that nonprovider facilities submit cost information to SSA/BHI. ²

¹Schupak v. Mathews, No. 75-1109 (D.D.C. September 17, 1976).

²41 Federal Register 49499, November 9, 1976, "Criteria for Determination of Reasonable Charges under the End-Stage Renal Disease Program."

Schupak appealed the District Court decision. On November 2, 1977, the Court of Appeals for the District of Columbia Circuit upheld Judge Bryant's decision of the previous year. In light of the passage of time, however, it ordered that the stay imposed by the lower court should expire at the end of 60 days. HEW, under this pending court order, managed to publish final regulations on the determination of reasonable charges on December 30, 1977, the last available working day before expiration of the stay. The department had now fully complied with the APA in establishing the basis for reimbursement of nonprovider dialysis facilities and the Secretary's authority to request cost data from facilities had been securely established.

BHI, therefore, in a May 1977 I.L., renewed its request to dialysis facilities for cost and statistical data. It cited authority provided by regulations issued in final form in 1976, the development of which is analyzed in the next section. The pertinent section of these regulations required dialysis facilities, as a condition of approval, to furnish data and information "in the manner and at the intervals specified by the Secretary, pertaining to its ESRD patient care activities and costs." A follow-up I.L. in September 1977 noted that submission dates not specified in May were to be within 90 days of the end of the facility's fiscal year or the date of issuance of the I.L., whichever was later. If noncompliance persisted, BHI threatened, "the Medicare Regional Office may take action to terminate the coverage of the facility as a provider of renal services."

Noncompliance did persist. In response, Medicare issued an I.L. in March 1978, 4 "requesting that all renal dialysis facilities

Schupak v. Califano, unpublished (D.D.C. 1976), affirmed (D.C. Cir., 1977).

²42 Federal Register 65174, December 30, 1977, "Subpart E--Criteria for Determination of Reasonable Charges; Reimbursement for Services of Hospital Interns, Residents, and Supervising Physicians."

³I.L. 77-14(A), "Submission of Renal Dialysis Facility List and Statistical Information," May 1977.

⁴I.L. 78-9(A), "Submission of Renal Dialysis Facility Cost and Statistical Information," March 1978.

report their costs and other statistical information to the Health Care Financing Administration." Citing authority from final regulations issued December 30, 1977, as well as those issued in 1976, the initial cost questionnaire was to be submitted no later than March 31, 1978. Sanctions were indicated: "Any nonprovider renal dialysis facility failing to submit the requested cost information within the specified time period will be subject to a suspension of its Medicare reimbursement." If a facility failed to submit data by March 31, the intermediary was instructed to initiate steps leading to suspension of payment of all bills from it received after April 30.

Schupak filed for a preliminary injunction in the U.S. District Court for the Eastern District of New York enjoining the HEW Secretary from enforcing the I.L. and challenging the legal validity of the December 30, 1977, regulations. The government asked the court to dismiss the complaint, or transfer the case to the D.C. District Court. Judge Jacob Mishler, after reviewing procedural irregularities in the earlier D.C. case, upheld Judge Bryant's decision as "sound and wellreasoned." He concluded that the reimbursement rate and the authority of the Secretary to set it were "in full conformity with the mandates of the Social Security Act and the expectations of Congress when it enacted the ESRD program." The Secretary's resort to cost as a factor in determining reasonable charges, he held was "clearly consistent" with his responsibility to the nearly 25 million beneficiaries whose voluntary contributions accounted for nearly half of the Part B Trust Fund. Judge Mishler found the I.L.s exempt from the APA rulemaking requirements. He granted the HEW request to dismiss Schupak's complaint.

This final confrontation was a tension-filled episode. Schupak, who treated 250 patients in his Queens facility, making it the second

¹The Health Care Financing Administration, created in early 1977, brought the Medicare Program from SSA and the Medicaid Program from the Social and Rehabilitation Service under the same administrative roof.

²Schupak v. Califano, No. 78-6231 (E.D.N.Y., April 11, 1978).

largest one in the country, had reportedly threatened to close the facility if Medicare payments were suspended. Because no National Medical Care facilities had yet complied with the cost data request, and because Schupak was president, there was a good deal of anxiety among Washington officials about the seriousness of the threat and how many NMC facilities might join Queens if the threat materialized. Soon after Judge Mishler's decision, however, Schupak informed HCFA that he would comply with the request for data.

It would be some time, however, before data were actually collected from all facilities. Predictably, the data would then be criticized, rightly so, in terms of quality. Further, the use of these data for altering the reimbursement screen for facilities would open yet another chapter in the continuing process of implementation.

OPERATIONS AND POLICY

What does this section suggest about the interactions between operations and policy in the operational stage of implementation? First, unlike the time-limited planning stage of implementation, the operational stage tends to be open-ended about time. It is difficult to set deadlines. Many pressures prolong consideration of issues and delay action. And it is extremely hard to meet deadlines if they are set.

Second, where policy formulation in the legislative arena and policy planning in the executive branch are focused on a few key actors who are central to controlled decision processes, decision—making in the operational stage is distributed across all the actors in the entire administrative system and all the issues in the implementation problem structure. Control is impossible, coordination is difficult, and even keeping track of events is a burdensome task.

Third, operational planning tends to be squeezed severely by policy planning in the time before the operational stage. Concurrent

^{1&}quot;Facility in Queens Threatens to Close 'Kidney' Machines," New York Times, March 19, 1978, p. 40.

policy and operational planning is possible only to a limited degree because operational planning is contingent on the outcomes of policy planning. Typically, critical but unresolved operational planning issues will be pushed into the actual operational stage of implementation.

Operational planning issues that are not resolved until the operational stage invariably create start-up problems, which generate costs of varying kinds that affect implementation. Start-up costs, if severe, generate anger among beneficiaries and important constituency groups, who may as a result force policy and procedural modifications or may inhibit options in policy development. Although not easily measurable, the relative costs and benefits of start-up problems of varying magnitudes deserve serious policy attention by all those concerned with successful implementation. Cash-flow start-up problems are perhaps the most difficult to avoid but also the most costly.

The inadvertent omission of critical issues in policy planning may lead by default to reliance upon preexisting, but inappropriate "standard operating procedures" for controlling operations, as was true for home dialysis. Or it may shift the issue from the legislative arena to negotiations between agencies, as in the VA case.

Policy revision and development in the operational stage may arise from several sources. Policy change may occur by the relatively easy exercise of administrative discretion, and determined political or constituency opposition to a policy—especially if coupled with the threat of litigation—may force policy change. Interagency negotiations may lead to a bureaucratic stalemate requiring intervention by the legislative branch to resolve important policy disputes. Policies arising inadvertently may, nevertheless, require legislation in order to adapt them to new realities. The legislative process requires time; its outcome is highly uncertain and is highly political.

The exercise of administrative discretion that powerfully affects the fortunes and rights of important constituents will be challenged in court both on grounds of procedural adequacy and substantive reasonableness. At a minimum, litigation delays the full and

confident assertion of authority by administrators. At worst, it may induce accommodating behavior to parties whose interest diverges from broader norms of the public interest. Surrey has noted the well-developed role of the Tax Court in the implementation of tax law. The five-year process definitively establishing the Secretary's authority to reimburse nonprovider dialysis facilities on the basis of charges related to cost, and to require the submission of cost data from such facilities, points to the clear, less developed, but emerging role of the courts in the implementation of health financing legislation.

¹S. S. Surrey, "Treasury Department Regulatory Material under the Tax Code," *Policy Sciences*, Vol. 7, No. 4, December 1976, pp. 505-518.

VI. THE ESRD LONG-TERM PROGRAM: PLANNING

The primary distinction between the interim and long-term ESRD programs has been substance, not sequence. The interim program, addressed in Sections III and IV, focused on reimbursement issues, the latter on the "medical" issues of the organization of the delivery system. Although the nature of the long-term program had its origins in the KDCP antecedents to the 1972 legislation, active planning began in mid-1973. This section considers the long-term program planning issues as they evolved over a four-year period.

The purposes of Section 299I were

- o To guarantee near-universal access to medical care;
- o To control the costs of delivering that care; and
- o To insure the delivery of high-quality care.

The reimbursement-oriented interim program sought to guarantee access by making a near-universal benefit available to terminal patients requiring a nonelective treatment to continue living, by paying facilities and physicians to treat such patients, and by permitting treatment facilities to grow in number and size relative to patient population growth. Cost containment was to be accomplished through the screen on allowable costs or charges for out-patient maintenance dialysis, though the disincentives to home dialysis somewhat undermined this objective. The implicit assumption of the interim program was that the quality of care would be insured by skilled physicians trained in the nephrology subspeciality of internal medicine. For the interim program, the relationship between ends and means was relatively clear.

The long-term program embraced these same three objectives, but the relationship between ends and means was much less clear. Access, for instance, was to be served by an organizational entity, the network, and not left to patients, physicians, and facilities. Cost containment was to be aided by minimum utilization requirements, though the interaction of these with the incentives of the reimbursement screen was barely acknowledged, let alone analyzed. Quality of care was to be served by medical review boards, a conceptually clear relationship with a basic problem of feasibility. The entire long-term program was to be served by an information system designed and operated before its objectives and users were clearly established.

The implementation problem structure for the long-term program, around which planning efforts were organized, included

- o Minimum utilization rates for covered services;
- o Medical review boards "to screen the appropriateness of patients for the proposed treatment procedures";
- o ESRD networks of dialysis and transplantation facilities; and
- o An ESRD Medical Information System to support medical review, networks, and higher level officialdom.

Policy and operational planning for the long-term program were marked by four milestones: the issuance of the final policies by the HEW Secretary on April 17, 1974; the publication of a notice of proposed rule making (NPRM) on July 1, 1975; the publication of final regulations on June 3, 1976; and the announcement of a funding decision about networks on August 27, 1977. The planning process is analyzed in terms of these events in this section.

THE FINAL POLICIES

The early 1973 draft regulations prepared by the Division of State Operations of BHI included a commitment to the regionalization of renal services. The February draft incorporated NKF and KDCP thinking about a stratified system of care. 1 The April 25 draft

¹National Kidney Foundation, "The Optimal Facilities Necessary for Diagnosis and Management of Patients with End-Stage Renal Disease," Report prepared for Regional Medical Programs Service, HEW, June 13, 1972; and Kidney Advisory Committee, Joint Commission on Accreditation of Hospitals, "Optimal Criteria for End-Stage Kidney Disease Care," Journal of the American Medical Association, Vol. 226, No. 1, October 1, 1973, pp. 45-49.

required participating hospitals to coordinate efforts with other facilities through "network agreements" within geographic areas.

Klar, the primary advocate for networks within HEW, first outlined his views in May 1973, recommending a kidney disease network coordinated by a "kidney treatment center." But the clearest statement of his views was a June 7 memorandum he wrote for Assistant Secretary Edwards. A central "condition of participation" for facilities was to be their formal organization into networks, which would contain costs by insuring adequate utilization of facilities and efficient distribution of scarce resources. Quality of care would be guaranteed by matching a high level of professional skills to a high volume of treatment. The central "kidney treatment center" would administer medical review boards having three functions: (1) approval or disapproval of individual patient selection, (2) review of therapeutic decisions, and (3) monitoring and review of ongoing patient care. Each center would serve a population of 500,000, would have affiliations with limited care and self-care maintenance dialysis units, and would have a transplant center serving a population of 2 million. There would be a national limit of approximately 100 transplant centers, but no limit on dialysis units. Expert professionals on a "national renal disease review board" would develop criteria for selecting qualified institutions and for recommending medical review guidelines.

Klar, in June 1973, before issuing the interim regulations, advocated announcement of the long-term organizational commitment to networks, concurrent with publication of the regulations. He drew no support from BHI, encountered opposition from the Deputy Assistant Secretary for Planning and Evaluation (Health), Stuart Altman, and secured no approval from the Secretary.

¹Memorandum from Assistant Secretary for Health to the Secretary, "Kidney Disease Benefits Under Medicare--Policy Issues, Summary," June 7, 1973.

In early July, the HEW health agencies were asked for comments on the June 7 memorandum. The Health Resources Administration (HRA) supported networks on both cost control and quality assurance grounds:

The long term plan proposes a program which limits facilities and structures them into treatment networks. This is based on tested models which have been developed through demonstration projects by agencies now within BHSRE [Bureau of Health Services Research and Evaluation]. Additionally, the concept of limiting certification for reimbursement of secondary and tertiary treatment facilities is based on more than subjective impressions. There are data, developed within BHSRE from existing registries, proving that minimum utilization rates do result in definite economies of scale with documentable cost savings. More profoundly, data show that CRD [Chronic Renal Disease] institutions exceeding minimum utilization rates (established with CRD expert input) provide better care - as indicated by patient mortality rates - than institutions which do not meet recommended minimum utilization rates. In fact, in transplantation, patient mortality at institutions performing fewer than 25 transplants/year is twice that at institutions performing 25 or more per year. Thus, objective evidence in both cost containment and quality of patient care argues strongly for strict adherence to the concept of limiting the number of facilities to assure optimal utilization.²

The network approach provided "the first opportunity for the federal government to develop regulations that will truly regionalize health care facilities" (emphasis added).

In mid-September, BQA concurred with the network approach, with limiting facilities on the basis of population, and with requiring

Memorandum from Acting Director, Office of Program Operations, H, and Acting Director, Office of Policy Analysis and Research, H, to Director, NIH; Administrator, HSA; Director, CDC; and Commissioner, FDA, "Implementation of Kidney Disease Treatment Program," July 2, 1973.

²Memorandum from Acting Administrator, Health Resources Administration, to Acting Director, Office of Program Operations, H, and Acting Director, Office of Policy Analysis and Research, H, "Implementation of Kidney Disease Treatment Program," n.d.

stratified medical review responsibilities. 1 It argued, however, for the transplant center, not the "kidney treatment center," as the center of the network: "It is logical that the highest stratum in the network be considered the focal point of the system." BQA also argued for a national ESRD information system.

BQA's fledgling ESRD unit 2 in early November set forth its detailed justification of networks. The justification included the "strong arguments for an organized delivery system" made by "recognized experts" and the demonstration by the PHS in the previous decade "that the most effective delivery system of ESRD care is a stratification of hospitals and other health facilities into an organized network." Avoidance of "uncoordinated development and duplication of resources" now required "careful planning" and resource allocation to insure access, facility utilization, quality treatment, and reasonable costs. Network size, which might encompass one state, several states, or a single metropolitan area, was to be determined by "medical service areas, referral patterns, and geographic considerations." Networks would include kidney disease transplant and dialysis centers, renal dialysis centers, and three types of maintenance dialysis centers--limited care, self-care, and self-care training--plus home dialysis, organized into a stratified system, with arrangements for

¹Memorandum from Acting Director, Bureau of Quality Assurance, to Acting Director, Office of Program Operations, H, and Acting Director, Office of Policy Analysis and Research, H, "Comment on OPAR Proposals for Long-Term Implementation of Kidney Disease Treatment Program Under Medicare," September 18, 1973.

The July 2 H memorandum acknowledged that administrative responsibility for the long-term program had to await establishment of long-term policies; it was assumed, however, that BQA would "retain the responsibility for being the lead office in providing and arranging professional support in H to the BHI as the program advances from interim to long-range status."

³Memorandum from Acting Administrator, Health Services Administration, to Assistant Secretary for Health, "The Medicare End Stage Renal Disease Program, P.L. 92-603, Section 2991--Policy Issues--ACTION," November 7, 1973.

cooperation and sharing among facilities along "a progressive continuum of diagnosis, treatment, and follow-up services to ESRD patients."

It would be necessary to limit transplantation centers to a population base of perhaps 2 million and a minimum utilization rate of 25 or more kidney transplants per year. Using these criteria might reduce the number of transplant centers from the 140 approved for reimbursement under the interim program to approximately 100. But such a step was justified on the grounds that large transplant centers experienced better patient survival and graft survival. The BQA memorandum stated:

Analysis of kidney transplantation data accumulated over four years by the National Transplant Registry (American College of Surgeons) reveals that transplant facilities performing fewer than 25 transplants per year had, in the fourth year of analysis (1971) twice the patient mortality than centers which performed more than 25 transplants per year. In addition, the organ (graft) function statistics from those facilities which perform less than 25 transplants per year are significantly lower than for those facilities which performed 25 or more transplants per year.

This paragraph rather neatly suppressed the uncertainty behind the quoted statistics.

In 1968, the American College of Surgeons (ACS) Organ Transplant Registry reported that transplant graft (or kidney) survival results for large and small centers "appear to be equal," the size criterion being 30 transplants performed between January 1, 1966, and January 1, 1968. In its spring 1973 newsletter, the registry updated its results, classifying those centers performing more than 100 transplants before 1970 as large. "Current comparisons continue to corroborate the former study," that is, to show no difference

^{1&}quot;Sixth Report of the Human Kidney Transplant Registry," Transplantation, Vol. 6, No. 8, November 1968, pp. 949-950.

between large and small centers. Within the KDCP, however, a young surgeon, Dr. J. D. Linehan, noted that the ACS had failed to compare large and small centers directly but, instead, had compared large centers with all centers, so that one could logically infer that small centers had inferior survival results. 2

Linehan convinced the ACS to disaggregate their data, which was done in The 11th Report of the Human Renal Transplant Registry. 3 Using a size criterion of 25 transplants yearly, the data showed "that there were no significant differences between the two groups of institutions during the years 1968, 1969, and 1970. In 1971, however, significant differences (p < .001 by the chi-square test) emerged for both patient and graft survival. One-year patient survival was 83 percent for large centers and 73 percent for small ones; one-year graft (transplanted kidney) survival was 68 percent for large centers but only 51 percent for small ones." Although large centers showed a steady increase in patient survival over the four years, they experienced no corresponding improvement in graft survival. The ACS report acknowledged that no effort had been made "to determine the merits of cadaver or living donors." Because it was widely known that many large centers generally favored living donors rather than

^{1&}quot;Spring Newsletter 1973," ACS/NIH Organ Transplant Registry, March 1973, Newsletter No. 10, Chicago, Illinois, pp. 1-2.

²Memorandum from J. D. Linehan, M.D., Health Consultant, KDCP, to Harold Margulies, M.D., Director, Regional Medical Programs, "Kidney Transplant Survival Statistics," May 25, 1973.

³"The 11th Report of the Human Renal Transplant Registry," Journal of the American Medical Association, Vol. 226, No. 10, December 3, 1976, p. 1199.

A curious footnote to the critical table of the 11th Report acknowledged: "This table is based on registry data as analyzed by the registry by J. D. Linehan, M.D., Health Consultant, Regional Medical Program, Rockville, Md." Because Linehan's close colleague, Dr. Jimmy Roberts, had helped draft the BQA memorandum, which cited the ACS Registry as authoritative, a fuller explanation of Linehan's role in analyzing the ACS data might have been expected.

cadavers, the failure to distinguish results along this dimension meant that no true comparison of large and small centers was possible.

But the BQA memorandum did not discuss whether the 1971 registry data represented a clear trend or a statistical aberration. Nor did it discuss any other problems with the data. It simply "voted" for large transplant centers. An ideological preference for large centers prevailed over the absence of supporting data.

These several memoranda reveal the underlying assumptions of the health professionals in HEW. First, they were highly critical of the unregulated disarray of "private" medicine. Klar, for instance, in November 1973, criticized the all-too-frequent "uncoordinated and disorganized proliferation of health care resources, without sufficient regard to need, efficiency, and collaboration." Second, there was a deep sense of need for, and belief in the capability of, organizing effective health delivery systems. Klar affirmed that "the integration of different types of facilities into organized networks seems essential in order to assure appropriate access to health care resources" and that matching the networks' resources to patient demands "seems essential in order to assure the appropriate distribution of health care resources." Third, there was a deference to expert opinion, as represented by academic medicine, which seldom questioned underlying assumptions or supporting data. For these reasons, no challenge to the network concept arose from the health agencies of HEW.

Questioning did come from BHI. Wolkstein responded critically to BQA's justification for networks, focusing mainly on the difficulty of applying substantive conditions of participation as applied to facilities, to networks per se, or to denying a facility the right to participate because it had not organized itself into a

¹R. M. Klar, Remarks at the annual meeting of the National Kidney Foundation, November 16, 1973.

network. The conceptual need for networks seemed to BHI to be for "affiliations and arrangements" among institutions providing dialysis, transplantation, and supporting services which guaranteed the coordination of basic services. Such arrangements could easily be required of facilities as conditions of participation, though "placing participation standards on networks requires the establishment of new entities not now at all well defined. . . . "Wolkstein also criticized the population base criterion:

Is it a practical matter to apply a test of population base service as a condition of participation, i.e., is this population base generally measurable—e.g., how do you calculate the base for the various institutions in Boston, New York, Philadelphia, or Rochester, Minnesota? Couldn't all transplant units allege an intention to serve a large population? If you can't apply the concept, what is the intended use?

The question, as time would reveal, was far from a trivial one.

Outside HEW, the physician reimbursement controversy drew attention. Within the department, that and related reimbursement issues were merged with the organizational issues into one complex package being developed for a policy decision by the Secretary. Assistant Secretary Edwards, in mid-February, transmitted two documents to HEW agencies for comment—one dealing with reimbursement issues, the other with organizational issues for the long-range program. ²

The organizational document, prepared jointly by Klar, Wolkstein, and Goodman, was one on which Edwards was seeking concurrence from others. The first of several policy issues addressed the need for

Memorandum from Irwin Wolkstein, Deputy Director, Program Policy, BHI, SSA, to Sheridan L. Weinstein, M.D., Director, Bureau of Quality Assurance, Health Services Administration, "Memorandum of 11/7 to Dr. Edwards Concerning Conditions of Participation for Renal Dialysis and Transplant Facilities," November 23, 1973.

²Memorandum from the Assistant Secretary for Health to See Addressees, "The Medicare End-Stage Renal Disease Program, Section 299I (P.L. 92-603)--Final Policies - ACTION," February 14, 1974.

³Goodman assumed leadership of the BQA ESRD unit in January 1974.

regulations to create networks for facility coordination. Although such regulations would not require "absolute denial of payment" where networks were not immediately developed, steps would be taken wherever possible to support network formation. Networks would aid patient access to care "through coordinated patient referral systems" and the effective utilization of both equipment and medical personnel. Their functions would be phased in over time: first would be facility certification; next, medical review boards; other responsibilities could be added as feasible. Reimbursement for transplantation would be limited to facilities serving a minimum population base and meeting a minimum utilization rate; the "reasonable approach" advocated would require a minimum of 15 transplants per year increasing to 25 at a later time. Similarly, renal dialysis centers were to be limited to about 400, based on population areas of 500,000, thus achieving a minimum utilization rate "because all patients (both transplant and dialysis) will be referred to this type of facility for advanced and costly diagnostic and treatment procedures." Recommendations were general for minimum utilization rates for maintenance dialysis facilities: they were to be sufficiently flexible to allow for urban and rural differences; and they should encourage "reasonable economies of scale" without creating incentives to hold patients in institutional dialysis when they ought to be referred to home dialysis or to transplantation. Also recommended were local (network) medical review boards, regional medical review boards, and a national advisory committee.

Between mid-February and mid-March 1974, internal HEW differences were resolved and incorporated into a March 18 memorandum from the Assistant Secretary for Health to the Secretary. It contained the essentials of the final policies announced by Weinberger on April 17.

¹ Memorandum from Assistant Secretary for Health to the Secretary, "The Medicare End-Stage Renal Disease Program--Final Policies--ACTION," March 18, 1974.

The final policies set forth the organizational framework for the long-term ESRD program; four issues were addressed—the network approach, minimum utilization rates, medical review boards, and professional consultation.

"Networks" were described as "an integration of hospitals and other health facilities" into organized patterns of delivery of care. Their need arose from the complexity of treating end-stage renal disease patients: the professional skills and facilities needed to treat patients required "a deliberate means of assuring cooperation and coordination." The PHS Kidney Disease Control Program, it was claimed, had demonstrated that network organization was "the most effective delivery system" for ESRD care, and provided assurance of access, "coordinated patient referral," and efficient allocation of equipment and personnel. Moreover, this approach had been advocated by committees of the NKF and the Joint Commission on Accreditation for Hospitals. 1

Network organization was to be based upon "medical practice patterns" for population bases of at least two million and would include the institutional capacity for providing the "full scope of ESRD diagnostic and therapeutic services." A data system would be developed for "monitoring patient care," and facilities would be required to participate in "a prospective patient transplant registry" and "a dialysis and transplant outcome registry." The ambitious aspiration was voiced that "each network will have to demonstrate the capability of exercising managerial direction over the professional and administrative aspects of the network's operation." "Coupled certification" of not only individual facilities but also the network to which all belonged was advanced as an expected condition of coverage. Designation of network areas was to be a departmental function, while internal network design was to be performed at the local level.

¹That these committees were chaired by the same physician and consisted of essentially the same membership was overlooked.

Facility and network certification for participation in the Medicare ESRD program would be based upon minimal utilization rates, especially for transplantation services, and "a suitable population base." The alleged benefits would be increased access, improved quality of care, and cost containment.

Local medical review boards (LMRBs) were to be developed at the network level to fulfill the statutory requirement of "review of appropriateness of patients for proposed treatment procedures," and the further requirements of utilization review and quality assurance. Once functional, the LMRBs were to become "an integral part or agent of Professional Standards Review Organizations."

The conflict surrounding the ESRD program in its initial year strongly suggested the need for improved means of consultation between the government and the medical community. The final policies indicated that the ten HEW regional offices and the national PSRO council should develop means within existing structures "to assure ongoing consultation with the renal disease professional and patient groups representing the regions and the country as a whole." But no provision was made for a national advisory body.

The portion of the final policies dealing with organizational issues was advocated by Klar in H, supported by Goodman in BQA, acquiesced to by Wolkstein in BHI, and was supported widely by the medical community and the health agencies of HEW. The task of converting secretarial policy into operational reality now fell to Goodman and the BQA's ESRD unit.

NOTICE OF PROPOSED RULE MAKING

The responsibility for drafting the proposed regulations for the long-term program fell mainly on BQA. Klar, for instance, saw the final policies as completing his responsibility and expected others to implement them. BHI retained formal authority for issuing Medicare regulations, but for the moment was not primarily concerned with organizational issues.

The ESRD unit in BQA, however, did not immediately begin drafting regulations, but instead prepared an "implementation plan," dealing

with networks and their coordination, relationships between the ESRD and PSRO programs, the ESRD medical information system, and an implementation timetable.

It was assumed that the plan should "guide the operation of certain aspects of the program until final regulations are promulgated."

Klar's reaction to the plan revealed differing views of the longterm program, a communication gap between H and BQA, and the absence of established working relationships among the health organizations of the department. First, the plan emphasized the special character of the ESRD program, while Klar argued that the most important problem was to determine how the program "fit into other Departmental activities." Second, the plan specified how the ESRD medical review boards would fulfill certain functions of the PSROs and be supported by them, while Klar argued that ESRD network designation and design must consider the needs of both programs. Third, the BQA plan identified a number of responsibilities for the Regional Health Administrators, while Klar clearly favored central office control "to synchronize activities with PSROs and CHPs." Finally, the plan recommended creating a regional renal consultant panel to advise each RHA and a national ESRD Advisory Committee to advise the Secretary. Klar noted that separate advisory groups had been considered and rejected in developing the final policies, that the statement "the ten HEW Regional Offices as well as the National PSRO Council will establish appropriate mechanisms within their existing structures" meant no separate advisory groups, and that BQA's recommendation was contrary to stated and agreed policy.

¹End-Stage Renal Disease, BQA, "Implementation Plan for Coordination and Medical Review of Care to End-Stage Renal Disease Patients," July 1974.

²Memorandum from Dr. Ronald M. Klar, Associate Director, Office of Policy Development and Planning, through Dr. Harry P. Cain, II, Acting Director, Office of Policy Development and Planning, to Dr. Henry E. Simmons, Deputy Assistant Secretary for Health, Quality Assurance, "Implementation Plan for Coordination and Medical Review of Care to End-Stage Renal Disease Patients," July 23, 1974.

One matter was resolved by this exchange. The implementation plan had proposed that the medical review boards be given responsibility for medical review and coordination of network activities. Klar suggested restricting the responsibility of these boards to medical review and establishing network coordinating councils for coordination purposes. This suggestion was accepted and both councils and boards became elements of networks from then onward.

BQA revised the implementation plan once, while preparing the initial draft of the proposed regulations. The HSA administrator distributed both documents widely within the department by a memorandum of September 30, 1974. But because the plan had no official status and HSA had not asked for concurrence, it soon ceased to draw comment. Attention focused instead on the draft regulations.

Wolkstein commented on the initial draft regulations to Goodman in early October, expressing concern about the "structure, function, and characteristics" of networks. One concern was the relationship of ESRD networks to "existing or developing agencies and organizations performing similar functions," namely, health planning agencies and PSROs. Second, as a strategic consideration, Wolkstein felt that networks should perhaps emphasize medical review initially and not be overburdened with the coordination function. He was also concerned that there be a "careful delineation of functions and relationships" between professional consultative groups, on the one hand, and the government with statutory obligations on the other:

The proposed functions of the network coordinating council and the medical review board need to be framed in language

¹Memorandum from Administrator to Addressees, "Review and Comment on Draft Regulations and Procedures for the Long-Range End-Stage Renal Disease (ESRD) Program," September 20, 1975.

²Memorandum from Deputy Director for Program Policy, BHI, to the Director, ESRD Unit, BQA, "Comments on Draft Regulations and Procedures for the Long-Term ESRD Program," October 7, 1974.

which will realize objectives in a way that does not appear to exceed legal authority or imply acceptance of decisions where there may be conflict of interest.

Beyond these issues, the questions about the geographic domain of a network prompted Wolkstein to ask, "How is the network's 'service area' most usefully defined? What real community does the network serve?" Finally, he raised the issue of network funding: medical review could possibly be reimbursed through "a charge against participating facilities' incurred expenses," but the reimbursement of planning and other activities appeared to pose problems.

The HSA Administrator, Harold Buzzell, formally transmitted on November 12 a revision of the proposed regulations to Thomas Tierney, Director of BHI, for clearance and submission for publication to the Federal Register. Declaring their publication "an urgent matter," Buzzell requested Tierney to "expedite the necessary clearance procedures" and to approve the proposed joint memorandum from the SSA Commissioner and Assistant Secretary of Health as the instrument for sending the regulations to the Secretary. This step set in motion a redrafting process between BQA and BHI: a formal proposal, prepared by BHI, was started through the SSA formal clearance process the following February; and on May 5, the SSA Commissioner signed and sent to the Secretary the proposed Notice of Proposed Rule Making.

Planning for networks before the final policies had been an abstract exercise. In preparing proposed regulations, however, the need arose to designate specific geographic areas as networks. Conflict then focused on the boundaries of these particular areas as planning became concrete.

The designation of network areas proceeded as a separate, though concurrent, task from the regulation writing. BQA initiated the "network identification" process in July 1974. A memorandum to the ten regional health administrators (RHAs) gave them responsibility

¹Memorandum from the Administrator to the Director, Bureau of Health Insurance, BHI, "Proposed Regulations for Implementing the Medical Aspects of the Long-Term End-Stage Renal Disease (ESRD) Program," November 12, 1974.

for recommending network areas, outlined procedures to be followed, indicated the desired timetable, and set forth the bases for area designation. Each RHA was to convene an ad hoc group of expert consultants "to recommend geographic boundaries and component facilities" for ESRD networks. BQA acknowledged that regional offices were understaffed and short of funds and promised \$10,000 for each and more where needed. It also noted that local regional medical programs had been asked to provide "administrative support" to the designation effort, and that officials from both state and areawide comprehensive health planning agencies could serve as consultants.

BQA listed the "fundamental elements" of a network as at least one transplant center and facilities "which together permit a natural and smooth pattern of referral" of patients, take account of "existing referral patterns" and "informal networks," and have the flexibility to cross state and regional boundaries. In addition, networks would usually require a minimum population base of approximately two million, and should avoid dividing a county, a designated PSRO area, or a Standard Metropolitan Statistical Area. The application of these criteria was left to the RHAs and their consultants. The suggested timetable stated that consultants complete the preliminary identification of network areas by August 31, that RHAs submit their recommendations by September 30, and that BQA complete the designation process by November 1.

Meanwhile, BQA convened an ad hoc consultant group in early

August to discuss network identification, regulation development, and
the ESRD information system. Discussion of network identification
focused on the principles for area designation, especially on the

¹Memorandum from Director to Regional Health Administrators, Regions I-X, "Development of Networks for the Delivery of End-Stage Renal Disease (ESRD) Services," July 26, 1974.

 $^{^2}$ These criteria contrasted sharply with PSRO area designation criteria, also issued by BQA, for which the primary criterion was that they not cross state lines.

³Memorandum from Program Coordinator, ESRD Program, Dívision of Peer Review, to the Deputy Director, Program Policy, BHI, SSA, "Information Documents on the End-Stage Renal Disease (ESRD) Program and an Alert on an August 8-9 Meeting," August 1, 1974.

issue of having networks cross state lines. Consultant opinion was divided: the prevailing view favored crossing state lines, though strong opposition was also expressed. But positions on this issue derived from each consultant's local situation and reflected, first, an application of the state boundary criterion to that situation, and then a projection of preferences to the national scene.

The consultants also regarded the proposed timetable as far too short. When BQA first informed ESRD facilities of the identification effort in late September, though, the schedule had been changed to allow 10 to 12 weeks for regional office consultation and development of recommendations.

Even this change was inadequate, as a November 7 status report on regional office identification activity indicated. Selection of ad hoc consultants had occurred in six regions, while groups had been convened to select consultants in the other four regions. ESRD providers, official state health agencies, CHP and RMP representatives typically participated.

In fact, BQA did not receive network designation recommendations from some regions until January and February 1975. In the meantime, BQA had decided to attach the network area designations as an appendix to the proposed final regulations which had been completed and sent to BHI in December 1974 for the initiation of the SSA review and clearance process. Delay in network designation threatened delay in publishing the proposed regulations. BQA staff, therefore, actively intervened in the network designation process, negotiating differences where it was possible and making central office recommendations where it was not. A network area proposal was sent to BHI on February 24, 1975.

Notice from Michael J. Goran, M.D., Director, Bureau of Quality Assurance, to Providers of End-Stage Renal Disease (ESRD) Care, "Identification of Networks for Provision of ESRD Care," September 30, 1974.

²Memorandum from Alvin I. Goodman, M.D., Program Coordinator, ESRD, to Jonathan E. Fielding, M.D., Director, Division of Peer Review, "Status of Regional Office Activity in Convening Consultants to Assist with Identifying ESRD Networks," November 7, 1974.

Memorandum from Acting Administrator, HSA, to Director, Bureau of Health Insurance, SSA, "Designation of Network Areas for End-Stage Renal Disease (ESRD) Regulations," February 24, 1975.

The BQA transmittal memorandum discussed the issue of state boundaries versus Standard Metropolitan Statistical Areas (SMSAs) as a basis for network designation, revealing a consistent BQA preference for maintaining SMSA boundaries. In fact, only two were divided in the networks proposed by BQA. In several notable instances, however, RHA-proposed state networks were rejected by BQA in preference to preserving SMSAs on the grounds that SMSAs were, first, proxies for existing patient referral patterns and, second, were the legally authorized basis for the new health planning areas. 1

Interestingly, the minimum population base and number of transplant centers required of a network changed without notice or explanation. All drafts of the proposed regulations, including one prepared by BHI on February 7, required a population base of 2 million and at least one transplant center. But a March 20 draft required a population base of 3.5 million and at least 2 transplant centers. The transmittal memorandum constituted the closest thing to an explanation, alleging that one criterion "suggested" by BQA to the RHAs had been that networks "be large enough to perform internally the peer review" required by the final policies. This implied at least two transplant hospitals and a sufficient number of dialysis facilities to permit review by peers not directly providing care. In fact, this criterion had not been included in the initial guidance to the RHAs.

There were several outcomes. Initially, it had been thought that there might be as many as 100 networks. Now that the number had been reduced to about 30, an obvious adjustment was required. Second, if large metropolitan areas, for example, were divided into areas having populations of 2 million, then any excess transplantation capacity

P.L. 93-641, the National Health Planning and Resources Development Act of 1974, had included such authorization, but allowed for exceptions where state boundaries were crossed.

²Draft: Department of Health, Education, and Welfare, Social Security Administration [20 CFR Part 405] [Regulations No. 5], Federal Health Insurance for the Aged and Disabled, "Conditions for Coverage of Suppliers of End-Stage Renal Disease (ESRD) Services," March 20, 1975.

could not be trimmed or even contained because numerous centers might easily claim to be serving 2 million. Such claims, moreover, were most likely to emanate from low volume, academic medical centers, and might well lead to a related attack on the minimum utilization rate. Third, it was also realized that a single transplant center per network would mean less autonomy for individual dialysis facilities; two transplant centers would insure more autonomy. The historic deep divisions between dialyzers and transplanters could not be suppressed. As networks, which had been little more than an abstract concept, began to acquire material form, underlying conflicts within the renal community began to surface.

During May and early June 1975, substantial controversy surrounded the proposed regulations and made publication uncertain until decided by the Secretary in mid-June. On May 5, Robert van Hoek, Acting Administrator of HSA, asked Theodore Cooper, the new Assistant Secretary for Health, two questions about the desirability of delaying the notice of proposed rule making (NPRM) in its current form. The first addressed relationships between the proposed ESRD networks and proposed Health Service Areas (HSAs); because designation of the latter was nearing completion, it had been suggested that ESRD network designations be delayed accordingly. The second issue, van Hoek claimed, was that SSA had "altered its position" regarding the funding of Network Coordinating Councils (NCCs) and Medical Review Boards (MRBs), and now felt that these should be funded by separate contracts administered by BQA rather than through facility reimbursement. Consequently, van Hoek recommended publication "at this time" of a revised NPRM, which would establish a "utilization review" requirement for facilities, but would delay the creation of networks until after

The change in population base and number of transplant centers came specifically from Goodman, who did not wish his own dialysis unit to be beholden to a single transplant center.

²Memorandum from Acting Administrator, HSA, to Assistant Secretary for Health, "Alternative to the Designation of End-Stage Renal Disease (ESRD) Networks - ACTION," May 5, 1975.

the designation of HSAs. Cooper rejected the recommendation on May 9, 1975. Van Hoek subsequently concurred with the recommendation to publish the NPRM, but not without pointing out "that the resources which would allow us to implement [the regulations] are not yet available."

The relationship of ESRD networks to HSAs became the focus of controversy within HEW. John Ottina, the Assistant Secretary for Administration and Management, reluctantly concurred with publication "only because the regulations are of major importance and have taken so long to develop." But he was "deeply disturbed" that the 29 proposed ESRD boundaries corresponded neither to PSRO nor HSA boundaries, and crossed both state and HEW regional boundaries. He wrote:

If the presently proposed ESRD areas are not modified, DHEW will have implemented within a period of three years, three major new health planning/monitoring programs which require administration by geographic area, and none of these programs will have corresponding area boundaries. This outcome will be a tragic failure in terms of fostering administrative efficiencies and promoting the ease of obtaining, developing, transferring and utilizing comparable statistical data and other evaluative information among related programs.³

PSRO boundaries had been established, and HSA boundaries were being set by the governors, but ESRD network designation was within the Department's authority. "I find no compelling reason," Ottina wrote, "why ESRD areas should not correspond to at least PSRO boundaries." He strongly recommended to the Secretary that "H be directed to

¹Memorandum from Acting Administration, HSA, to Acting Director, Office of Program Implementation, Attention: Regulations Officer, PHS, "Proposed Regulations: Condition for Coverage of Suppliers of ESRD Services," May 16, 1975.

²Memorandum from Assistant Secretary for Administration and Management to The Secretary, "SSA - Notice of Proposed Rule Making - Conditions of Coverage of Suppliers of End-Stage Renal Disease (ESRD) Services - (20 CFR Part 405) - (Regs. No. 5) - ACTION," May 16, 1975.

^{3&}lt;sub>Ibid</sub>.

redesign ESRD areas to correspond at least to PSRO areas and where possible to HSA health service areas."

The Assistant Secretary for Planning and Evaluation, William A. Morrill, expressed nonconcurrence with the proposed regulations, citing the incongruity between ESRD networks and health planning "To announce a new, uncoordinated categorical health planning system for renal disease at this time will do harm to our past and future efforts to establish a comprehensive and rational health planning system." Specifically, ESRD network areas conflicted with HSA areas: the governors had submitted their proposed HSA designations on May 1, 1975, but some of the larger ESRD networks bisected a number of proposed areawide health planning areas. Although final HSA designations were not due until August 4, discussions with the governors on their recommendations were to occur in late June. "By proposing separate regional planning areas for renal services," Morrill wrote, "without regard to the health planning areas just designated by the Governors, the Department would unnecessarily and unwisely undermine State and local efforts to coordinate health care delivery." Furthermore, where the ESRD system vested certificate-of-need authority in the Secretary and planning responsibility with the NCCs, the health planning law vested certificate-of-need authority in state agencies and planning in the areawide HSAs. Morrill saw a clear need "to integrate these various regulatory and planning activities." He recommended that the proposed ESRD regulations be delayed approximately one month so that network areas could be made coterminous with health service areas. Concurrently, SSA and H should modify the regulations "to specify how the respective planning and regulatory roles of the Secretary, the Network Coordinating Councils, and the State and local health planning agencies will be integrated."

Memorandum from Assistant Secretary for Planning and Evaluation to The Secretary, "SSA Proposed Regulations Covering End-Stage Renal Disease," May 30, 1975.

Van Hoek sent Cooper a memorandum in early June responding to Ottina and Morrill's objections. Although he had recommended delayed publication one month earlier, van Hoek now found "compelling arguments" for publishing the NPRM "without delay." The network concept was not new or incompatible with either the PSRO or health planning concepts, but did require a population and provider base "which exceeds that required for either an HSA or PSRO." The proposed ESRD regulations and network boundaries, moreover, would not set precedents for HSA designations. And notwithstanding the imminent designation of HSAs, many months could pass before they became functional. In contrast, ESRD reimbursement "will continue along the medical referral lines which are well established" and which would become "more rational" to the extent that networks can achieve it. (In fact, reimbursement went to facilities and physicians for services to identified patient beneficiaries without reference to medical referral patterns.)

Whatever conceptual compatibility existed between ESRD networks and HSA areas, reality was something different. Only 8 of the 29 proposed networks were consistent with proposed HSA designations. In two cases ESRD networks divided a single-state HSA (such as Idaho) or one proposing two HSAs (one county, plus all other counties--for example, Nevada); and five inconsistencies reflected conflict between ESRD patient referral patterns and health planning assumptions. Ironically, 14 inconsistencies arose from the BQA effort to preserve interstate SMSA areas in anticipation of the HSA designations under P.L. 93-641. What BQA bureaucrats had preserved, political governors had rent asunder!

Cooper recommended immediate publication of the NPRM to the Secretary on May 23 if the proposed ESRD network boundaries were modified to conform more closely to HSA areas, and if language about the

Memorandum from Acting Administrator, HSA, to The Assistant Secretary for Health, "ESRD Regulations - BRIEFING," June 6, 1975.

²Memorandum from Acting Administrator, HSA, to Director, Bureau of Health Insurance, SSA, "Designation of Network Areas for End-Stage Renal Disease (ESRD) Regulations," February 24, 1975.

criteria for network designation were restored to the body of the regulations. Responding to the growing controversy within the Office of the Secretary, he suggested that the principal parties meet to negotiate differences rather than return the NPRM to the originating agency, a cumbersome and time-consuming process.

A meeting was held on June 9, convened by the Office of the Secretary, at which all parties were present. Cooper, later reviewing the meeting for the Secretary, noted that the "one remaining issue which must be resolved" was the relationship between the proposed ESRD networks and the proposed HSAs. 2 Acknowledging that approximately one-half of the proposed ESRD network boundaries were not congruent with proposed HSA boundaries, Cooper sought to explain and defend the NPRM. "One of the critical criteria we utilized" for network designation, he wrote, "was their potential congruity with HSAs" (emphasis added), but this eroded as HEW began to grant HSA waivers to the governors. But other critical criteria were also used, the most significant being "patient referrals patterns." Where these criteria conflicted, Cooper argued, congruence with HSA boundaries should yield to patient referral patterns. Furthermore, network boundaries were being reexamined and the discrepancies between them and HSAs could be reduced to approximately three to six networks. The assistant secretary stressed that publication of the NPRM would permit changes to be made during the 60-day public comment period, while delay would mean no regulations for another four to six weeks. Delay would also leave the department in an exposed and vulnerable position for hearings on the ESRD program that the House Committee on Ways and Means had scheduled for June 24, less than two weeks away. 3 Two years after the program had become operational, HEW was not eager

¹ Memorandum from Assistant Secretary for Health to The Secretary, "Long-Term Regulations for End-Stage Renal Disease (ESRD)," May 23, 1975.

²Memorandum from Assistant Secretary for Health to The Secretary, "The Timing of Publication - A Notice of Proposed Rule Making of the 'Long-Term' End-Stage Renal Disease Regulations (Subpart V) - ACTION," June 12, 1975.

³U.S. House of Representatives, Committee on Ways and Means, "Medicare's Kidney Disease Benefits Program," Hearings, 94th Cong., 1st sess., June 24 and July 30, 1975.

to appear on Capitol Hill without having published these long-ago promised regulations.

But the controversy generated a scrambling effort to redraw the ESRD network boundaries. By the time the HEW secretary approved the NPRM and sent it to the *Federal Register* for publication, 29 designated ESRD networks included only 9 that were unchanged from the February submission by BQA to BHI. The NPRM, with the modified appendix, was published on July 1, 1975.

The NPRM, elaborating the final policies, prescribed the role of ESRD networks, including medical review, minimum utilization rates, and health and safety requirements for ESRD facilities. An ESRD network would permit "an efficient pattern of referral" of patients among facilities providing "the full spectrum" of transplantation, in-patient dialysis, chronic maintenance dialysis, and self-dialysis training services. Network designation required a minimum population of 3.5 million and at least two transplant facilities. Membership in a network was both open to all facilities and required of all.

An NCC was to be established in each network whose members were to include one representative from each facility and, if not otherwise represented, other medical specialists. NCCs would prepare a written plan that included network objectives, methods of implementation, policies and procedures, and a list of facilities, the services it provided, a "quantitative estimate" of its capacity, and the name of its representative. They would also submit an annual report to the Secretary on the services provided by each facility, and on actual utilization rates, by facility, for the previous year and the anticipated rate for the next three years; participation by any

¹⁴⁰ Federal Register 27782, July 1, 1975, "Conditions for Coverage of Suppliers of End-Stage Renal Disease (ESRD) Services."

²The other specialists were to include a transplant surgeon, internist-nephrologist, pediatrician, urologist, psychiatrist, histocompatibility testing laboratory director, psychologist, dietitian, rehabilitation counselor, ESRD nurse, social worker, ESRD dialysis technician, and three "informed consumers."

facility at a substandard minimum utilization rate was to be explained. Anticipated relationships between ESRD networks and health planning agencies were discussed:

When the Health Systems Agencies (HSAs) required under P.L. 93-641 have demonstrated to the Secretary their capacity to assume responsibility for the functions described in this section, the Secretary may assign such responsibility to the HSAs. The Network Coordinating Council that had performed these ESRD functions may continue to perform such functions on behalf of the HSAs if they so request.

A Medical Review Board (MRB) consisting of five members was to be established by each NCC to review "the adequacy of patient selection of ESRD care," screen "the appropriateness of patients" for proposed treatment, review "the appropriateness of treatment plans for ESRD patients," and review "the appropriateness of services provided to patients" including ancillary medical services. It was also to respond to requests from carriers and intermediaries about "the appropriateness of unusual services," and to perform studies on "the organization and delivery of health care services to ESRD patients." The review functions were to be guided by professionally developed "norms, criteria, and standards" using "aggregate patient outcome data" developed by the national ESRD medical information system and data on individual cases from patients' charts. Facilities would be required to participate in the ESRD medical information system. The MRB was to recommend improvements in patient care to physicians and facilities; if inappropriate or substandard care persisted, it was to report "all facts" to the NCC and the Secretary.

Whereas the NCC was to coordinate with HSAs, the MRB was to coordinate with the Professional Standards Review Organizations (PSROs). Pointing to the future, the regulations stated:

¹These were to include a transplant surgeon, an internist treating ESRD patients, another physician participating in other aspects of ESRD care--like a urologist or psychiatrist--a registered nurse, and a social worker.

When a PSRO has demonstrated to the Secretary its capacity to assume responsibility for the reviews described in paragraph (c) (2) of this section, the Secretary may assign such responsibility to the PSRO. The Medical Review Board that had performed ESRD care review may continue to perform such review on behalf of the PSRO if the PSRO so requests.

Minimum utilization rates were indicated. For transplantation centers, 25 or more transplants per year would be required for unconditional approval, and 15 to 24 per year for conditional approval. Dialysis centers in SMSAs of 500,000 or more population were required to have the following standards: for unconditional approval, six or more dialysis stations averaging at least four and a half dialyses per station per week, and for conditional approval, six or more stations each averaging between four and four and a half dialyses per week, or four to five stations each averaging at least 4.5 dialyses per week. In SMSAs of less than 500,000 population, the standards for unconditional approval were three or more stations each averaging four or more dialyses per week.

The proposed regulations required other "health and safety" requirements, including facility compliance with federal, state, and local licensure and registration laws, facility governing body and management, medical records, physical environment, affiliation agreements with other ESRD facilities, written patient care plans, and provision for patient rights.

The process of publishing the NPRM revealed much about the bureaucracy. First, whatever the merits of the proven regional models for delivering ESRD care, such models were obviously of extremely limited use in the actual network design and area designation effort. Second, basing network areas on alleged medical referral patterns was little more than an a priori commitment to preexisting patterns of medical institutions and policies, frequently unsupported by adequate data. Third, the focus on preserving SMSAs because of their importance to emerging health planning areas and then ignoring the actual designation of such areas reveals opportunistic inconsistency, administrative incompetence, or both. Finally, the unwillingness to delay

publication indicates again the goad to administrators provided by the prospects of critical Congressional hearings.

FINAL REGULATIONS

The NPRM provided 60 days for public comment, during which 381 written communications were received. But so many were submitted after the deadline that HEW accepted them beyond the required period. Nearly 450 individual letters were received between July 1, 1975, and HEW's decision to cease considering any more.

In addition to written comments, efforts were made to exert influence in the writing of final regulations—direct appeals to executive branch officials, indirect appeals through Congressional channels, use of special access to the Secretary. For in entitlement programs, nothing governs so much as the regulations and hence nothing is so much the subject of political conflict as the language of those rules.

In this section, we analyze the development of minimum utilization rates for transplantation centers, summarize two controversial network area designations, and briefly note several last minute obstacles that were encountered before final regulations were published on June 3, 1976.

Minimum Utilization Rates for Transplant Centers

Minimum utilization rates presume a positive relationship between utilization and cost and utilization and quality. For surgical procedures, the presumption is that high volume results in better outcomes. The NPRM proposed that 25 or more kidney transplants per year be required for unconditional approval, and 15 to 24 per year for conditional approval. But the proposed standard failed to survive

Harold S. Luft, John P. Bunker, and Alain C. Enthoven, "Should Operations Be Regionalized? The Empirical Relation between Surgical Volume and Mortality," New England Journal of Medicine, Vol. 301, No. 25, December 20, 1979, pp. 1364-1369, present data on this relationship for 12 surgical procedures, not including kidney transplantation. See also William P. Longmire and Sherman M. Mellinkoff, "Regionalization of Operations," pp. 1393-1394 in the same issue.

the period of public comment. The final regulations stipulated that unconditional approval would be given to transplant centers performing 15 or more transplants per year, and conditional approval would go to those conducting 7 to 14 transplants annually.

Two factors lay behind this change. First, the data failed to show a relationship between the number of transplants performed each year and either patient survival or cost. Second, it was realized that the application of the NPRM criterion would eliminate many modest size academic transplant facilities, for which there was little enthusiasm in the medical community. The change in the final regulations reflected an earlier shift within the medical community relative to both factors.

In June 1971, the Regional Medical Programs Service convened a small group of transplant surgeons from several major medical centers, who generated a policy statement supporting the view that large centers were necessary for providing transplant services. One year later, the "Optimal Facilities" document stated: "The major criterion for designating a kidney transplantation center shall be its demonstration of potential ability to attract patients in sufficient numbers to maintain the competent expertise demanded by a superior program." That criterion was that it "should have the capability within 1 to 2 years of performing 50 or more kidney transplants per year."

The large center hypothesis endorsed by RMPS was essentially "sold" by them to BHI and others in HEW in early 1973 when the interim regulations were being prepared. The existing number of transplant centers in the United States was deemed adequate for the country's foreseeable needs, and by the "freeze" on facilities, no new transplant centers were approved in the "exceptions" process from early 1974 onward. Existing centers would have to increase volume over time to meet minimum utilization requirements.

^{1&}quot;Statement of the Ad Hoc Transplantation Policy Committee; Recommendation to the Regional Medical Programs," prepared in San Francisco, June 14, 1971. Though not an official document, this statement was nevertheless widely distributed.

The large center hypothesis was endorsed in the April 1973 draft and the August final version of the National Kidney Foundation's "White Paper." It called for unconditional certification of transplant facilities that had accomplished 25 or more transplants during 1972 and provisional certification for those performing more than 10 and less than 25 transplants annually. It also stipulated deferment of consideration of those centers doing fewer than 10 operations per year.

By the time the NKF submitted comments on the NPRM, however, if had done a $volte\ face$ on the issue of large transplant centers. In 1975, it recommended 15 transplants per year for unconditional certification, and 10 to 14 transplants per year for conditional status:

The higher limits for unconditional and conditional approval in the Proposed Rules will potentially threaten the status of a number of high quality but moderate size transplant programs now in existence. It could thereby diminish access to transplantation as well as availability of cadaveric organs. There is no persuasive evidence that transplant success, patient mortality or costs are significantly different in very large programs as compared with moderate size programs. In addition, the Proposed Rules tend to stress facility capability. This emphasis disregards the fact that in a number of large communities, the transplant activities of a group of transplant surgeons and nephrologists are carried out in a program format divided between two (or occasionally three) hospitals. Lowering the limits for conditional and unconditional approval therefore appears to be wise and appropriate in order to enhance the growth and development of high quality transplantation programs in the Networks. Ultimately, the quality of these programs will become the responsibility of the Network Councils and their Medical Review Boards.

The NKF shift clearly reflected the failure of the data to support the large center hypothesis, and also the views of "moderate size"

Letter from Jordan E. Ringel, Chairman, and James C. Hunt, M.D., President, National Kidney Foundation, to Mr. James B. Cardwell, Commissioner of Social Security, August 28, 1975, "Re: Proposed Rules, Conditions for Coverage, End-Stage Renal Disease, Department of HEW, Federal Register, Vol. 40, No. 127, Part II, July 1, 1975," with attached documents.

academic transplant programs—an important NKF constituency not fully represented in the 1973 White Paper exercise. The Southeastern Dialysis and Transplantation Association, for instance, endorsed the NKF position by direct citation, and the Renal Physicians Association called for "maximum flexibility in granting exceptions to utilization rate standards" in light of the inadequate documentation of the relation of number of transplants to cost and quality. In short, there was no longer any strong support for large centers from the academic medical community.

The government justified its retreat from the NPRM standard with a somewhat convoluted logic. In the preamble to the final regulations it noted: "A major comment was that there should be no minimum utilization rates because evidence is lacking that the number of procedures performed correlate either with quality improvement or cost efficiency."4 While conceding "a lack of conclusive evidence" on this relationship, the government still maintained that "it can be rationally assumed that such a relationship does exist." Beyond this defense of assumptions unsupported by evidence, however, the government acknowledged one very clear implication of the proposed rates: many transplant centers would be eliminated from further participation in the ESRD program if the NPRM standard were applied. "This adverse effect on access of care," according to the preamble, led to the decision to reduce the minimum utilization rate for transplant centers. In this instance, though, it was less a matter of patient access to transplantation facilities than access of the latter to government reimbursement.

On the issue of teams v. hospitals, the government rejected the NKF's suggestion and the final rule provided for certification of the facility.

²Letter from Wm. Way Anderson, M.D., Secretary-Treasurer, Southeastern Dialysis and Transplantation Association, to Mr. James B. Cardwell, September 8, 1975.

³Letter from John H. Sadler, M.D., President, Renal Physicians Association, to James B. Cardwell, August 28, 1975.

⁴⁴¹ Federal Register 22502, June 3, 1976.

Several observations can be made about this episode. First, the process by which expert medical opinion defines a normative criterion for the organization of health care services is sometimes remarkably casual and unsupported by empirical data. Second, the process by which expert opinion becomes dogma within the health arm of HEW can be very uncritical, more ideological than analytical. Finally, dogma so developed usually erodes over time without supporting data as "aggrieved" political interests force challenging data into the debate.

Finally, the controversy raises some troubling questions for policymakers. First, what relation does exist between the utilization of a surgical service and its cost and efficacy? And, second, how can that relationship be determined? The first question can only be answered empirically, and factors other than utilization are likely to be important determinants of cost and efficacy. The short answer to the second question is that careful analysis is required to establish the relationship, which implies a need for disentangling genuine expertise from professional bias in "expert medical opinion."

Network Designation Controversies

The written comments on the NPRM contained substantial support for the concept of organized ESRD networks, but controversy centered on specific designated areas. We summarize two controversies—New Jersey and Illinois—for what they reveal about policy planning for the long-term program. A longer analysis of each case is found in Appendix C.

New Jersey. This controversy centered on whether New Jersey should be divided and distributed among two other networks or whether it should be designated as a single-state network. The 1975 NPRM proposed dividing the state: Bergen County in the north was to be included with metropolitan New York as Network No. 25, while the rest of New Jersey, all of Delaware, and 35 counties of eastern Pennsylvania were proposed as Network No. 24. The map was redrawn in the 1976 final regulations, however, and the entire state was designated as Network No. 24.

During 1974 and early 1975, the consultants to Region II (New York, New Jersey, Puerto Rico, and the Virgin Islands) recommended

and the regional health administrator endorsed New Jersey as a separate network. In Region III (Pennsylvania, Delaware, Maryland, Virginia, West Virginia, and Washington, D.C.), however, the inclusion of New Jersey was discussed but not recommended. But BQA intervened and the NPRM proposed to divide the state.

The conflict between New Jersey physicians and BQA hinged on whether Camden and southern Jersey were part of New Jersey or the Philadelphia SMSA. BQA argued that many institutions in the proposed network area had long-standing resource-sharing affiliations in order "to up-grade the quality of care, prevent the unnecessary acceleration of cost, and assure the access to quality care for its patients." It was also anticipated that the implementation of the health planning law would result in the designation of the Philadelphia SMSA, which included Camden, as an HSA. "It becomes imperative," wrote BQA, "that this SMSA be a part of the same ESRD network."

New Jersey physicians, on the other hand, claimed that state renal facilities had operated as a network since 1969, that statewide certificate-of-need existed and should not be disrupted, and that the state health planning agency had formally endorsed a single ESRD network. In short, existing affiliations among institutions supported the inclusion of Camden and South Jersey in a single network. ²

Although BQA had decided to divide New Jersey in February 1975, this was not announced until the NPRM was published on July 1. The controversy between BQA and New Jersey required the rest of the year for resolution. During that time, the New Jersey physicians mobilized the state's Congressional delegation, which bombarded HEW with numerous letters favoring a statewide network. The physicians met with Assistant Secretary Cooper in late September. HEW redesignated the state as a single network by the end of the year.

Op. cit., Memorandum, Acting Administrator, HSA, February 24, 1975, Tab C, "Issues in Network Area Designations."

²Letter from John P. Capelli, M.D., to Mr. Thomas Budstibner, Regional Office, Department of Health, Education, and Welfare, October 14, 1974, "Re: ESRD Hospitals in Southern New Jersey for Network Participation."

The outcome turned on several developments. First, New Jersey patient referral data showed greater reliance of South Jersey renal patients on New Jersey facilities, and less upon Philadelphia facilities, than earlier BQA data had claimed. Second, when the designation of Health Service Agencies was completed in September, the Philadelphia SMSA was divided—by the Delaware River, the New Jersey and Pennsylvania border.

Third, it was disclosed that Our Lady of Lourdes Hospital in Camden, which had applied for certification as a transplant center, had actually performed 31 operations between May 1974 and July 1975 and was projecting 35 to 40 transplants in calendar 1975 handily exceeding the standard proposed in the NPRM. Even more startling, the hospital had been reimbursed for these services by Medicare, though not yet certified for such purposes! Although Philadelphia, with several medical schools, had an excess of transplant centers, these facts confronted HEW with a practically irresistable demand. Lourdes was certified in November.

The advocacy by New Jersey physicians, supported by better data than BQA could assemble, by the Lourdes fait accompli, and by an aroused Congressional delegation, forced HEW to yield.

Illinois. This conflict, as with New Jersey, was over dividing Illinois among three networks or designating it as a single network. The NPRM recommended division: 68 counties of southern and central Illinois were to go in a Missouri-Kansas network, 3 counties in the Davenport, Iowa SMSA were to be part of an Iowa-Nebraska network, and the remaining 31 counties in northern Illinois were to be a network. In the final regulations, by contrast, the state lost only 7 counties—4 in the south to Missouri-Kansas and 3 to Iowa-Nebraska; the remaining 95 counties were designated as Network No. 15.

Two federal regions submitted different recommendations which BQA resolved. In Region V (Michigan, Ohio, Indiana, Illinois, Wisconsin, and Minnesota), both the consultants and regional health administrator proposed a single network. The recommendation from Region VII (Iowa, Nebraska, Missouri, and Kansas) was to include the 3 Illinois counties in the Iowa-Nebraska network and 34 counties of

southern Illinois with Missouri-Kansas. BQA accepted the first Region VII proposal and added 34 central Illinois counties to the second.

The heart of this dispute was over the criteria for organizing renal networks. The Region V consultants argued that networks were administrative entities that should not affect patient referrals, since some patients would always be near network boundaries regardless of where lines were drawn. Their rationale was also financial:

Organization of networks along state lines was dictated primarily by the reality of reimbursement needs for costs not covered by Medicare. Several state renal programs reimburse facilities for costs of dialysis patients not yet eligible for Medicare, and also reimburse the 20% not covered by Medicare. Subdivision of these states would jeopardize continued support of state renal programs.

Specifically, since 1967, Illinois had paid for dialysis and transplantation for its residents treated in state-certified facilities or in approved facilities in Indiana, Missouri, and Iowa. This program, widely regarded as a model, had created a sense of identity among Illinois physicians, a commitment by the Department of Public Health, and a belief that the state would become a single network.

BQA's reasoning resulted in a geographically elongated network proposal. Kansas and Missouri logically should be linked because of the Kansas City SMSA. It was necessary to include eastern Missouri to meet the two transplant center criterion. And since many Illinois residents came to St. Louis for dialysis, its southern counties should be part of the network. Finally, since central Illinois had strong ties to the south, it should be included as well.

The conflict between BQA and Illinois began in March 1975 and continued the rest of the year. Illinois physicians and the Department of Public Health mobilized the state's Congressional delegation. A blizzard of letters protesting the division of Illinois descended on HEW. In time, Illinois developed data showing that patient flow to

Letter from A. R. Lavender, M.D., Chairman, Ad Hoc Consultant Group, ESRD, to E. Frank Ellis, M.D., Regional Health Administrator, Department of Health, Education, and Welfare, Region V, Chicago, Illinois, January 3, 1975.

St. Louis came mainly from four southern counties. It was also pointed out that a large, multi-year HEW grant to Illinois had resulted in a state plan for development of medical education, and the proposed division for ESRD purposes would disrupt this HEW-supported effort.

Sustained advocacy by Illinois physicians and officials, supported by the state's Congressional delegation, by data which undermined BQA's position, and by the potentially disruptive effects on medical education, led HEW to modify its original proposal.

These two network designation controversies were not the only ones created by the NPRM. They illustrate, however, a number of problems in planning geographically based health delivery systems.

First, the criterion of patient referral patterns, though primary, was not always the dominant decision rule used by BQA. Moreover, no explicit methodology or process was developed by BQA for analyzing referral patterns, and when analysis was performed, the data were typically of low quality. Underlying this criterion was a commitment by BQA to existing referral patterns as normative guides to the future.

Second, the criterion of "preserving SMSAs" initially was a proxy for patient referral patterns. P.L. 94-641, the health planning law, reinforced the importance of this criterion because of the prominence it gave to the SMSAs. But the designation process in health planning was explicitly political in the statutory provision that governors be the principal designating agents. Consequently, multistate SMSAs were often divided by mutual consent of the respective governors. Furthermore, BQA's attempt to preserve multistate SMSAs failed to acknowledge that political opposition to ESRD networks would normally come from existing political jurisdictions, whereas practically no political support would be forthcoming from SMSAs.

Most intriguing was BQA's failure, even refusal, to consider the reimbursement implications that state network boundaries implied. Expensive therapy like dialysis and transplantation, even though covered by Medicare, can generate substantial financial burdens to patients through the co-payment requirement. Conceivably, as Illinois physicians argued, designation of state networks where strong state

renal programs existed would permit easier administrative links between state and federal governments on the issue of co-payment. The absence of BQA concern about this issue reflected the failure to acknowledge adequately that reimbursement and health care are closely related.

The BQA network designation often failed to take account of the medical care system of which ESRD was only a part. Frequently, as was true in New Jersey and Illinois, statewide planning had established a framework for the development of medical education within which efforts were being undertaken to achieve rational allocation of resources. BQA was forced to acknowledge the evolution of the medical care system at the state level because of political controversy, not by virtue of previous insight, interest, or concern.

Finally, the network designation process demonstrates the practical impossibility of developing and applying any set of criteria in a consistent manner to the entire country, or the practical necessity of inconsistency.

Publication

A joint BQA-BHI work group analyzed the public comments and negotiated agreement on changes between the two agencies. By early December, a target date of February 2, 1976, had been set for publishing the final regulations. In mid-January, however, Goran wrote to the HSA administrator, stating that BQA, BHI, and the Office of the General Counsel all agreed that changes from the NPRM were sufficient to warrant a second NPRM. He suggested a revised schedule, which, at best, would have delayed publication until July 1. But Assistant Secretary Cooper determined that the changes were not substantive, and transmitted the draft final regulations to SSA in late February for initiation of formal review. The SSA clearance process moved quickly, largely because BHI had participated in the work group, and Commissioner Cardwell signed and sent to the Secretary the final regulations package

¹ Memorandum from Director, BQA, to Acting Administrator, HSA, "Preamble to the Long-Term End-Stage Renal Disease (ESRD) Regulations," January 13, 1976.

on March 25, 1976. All that remained was formal clearance at the departmental level and the Secretary's approval of the regulations for publication.

Publication was again delayed, however, by a question from Marjorie Lynch, the HEW Under Secretary. Why, she asked, were the networks dividing so many HSAs and PSROs? The draft final regulations included eight network areas that divided HSAs. In response, six proposed networks were modified so they no longer divided the HSAs in question. In the case of the southern counties of Idaho, initially included in ESRD Network No. 5 and dividing the Idaho HSA, there were no ESRD facilities in these counties. A solution existed that respected HSA boundaries and did not disrupt patient referral patterns (southern Idaho patients were normally referred to Salt Lake City in Network No. 5). In cases like California, where two networks divided three HSAs, the justification for the proposed boundaries was persuasive. The final regulations, therefore, changed six networks—by moving a few counties in each instance—to conform to HSA boundaries.

But Lynch's question prompted her to ask why ESRD networks were necessary at all. Why not permit the HSAs, now becoming operational, to assume ESRD functions as part of their normal responsibilities? Assistant Secretary Cooper responded, thanking the Under Secretary "for the opportunity to explain why the ESRD regulations should be published as written." First, HSAs were not large enough to provide all levels of ESRD care without joining together, and thus forming network-size entities. Proposed ESRD networks were based upon patient referral patterns, which would be divided by relying upon HSAs. Integration of the ESRD networks and the HSAs, on the other hand, was required by the regulations. Cooper argued on the basis of how renal services were delivered, that the network concept was "the most cost-effective means of assuring effective planning for ESRD services," and that "the HSA concept would increase costs without without increasing benefits." In fact, no analysis supported this

¹Memorandum from Assistant Secretary for Health, to The Under Secretary, "SSA End-Stage Renal Disease (ESRD) Policy Regulations," May 20, 1976.

statement, which only reflected a tendency within H to support its preferences by using analytical language without doing the analysis. His final argument, closer to the mark, was that the network concept would prove "less disruptive to both providers and patients while assuring that the goals of the Department's ESRD program are met." The renal physician community, in fact, did not wish the ESRD program to be integrated into a health planning system. The Assistant Secretary reflected this preference.

The Under Secretary was persuaded. She signed the draft regulations for the Secretary on May 24, 1976, and they were published less than two weeks later.

The final regulations were issued on June 3, 1976, effective September 1. The bases of network area designation remained the 3.5 million population base and 2 transplant centers. Network boundaries were to be coterminous with HSAs and PSRO areas "to the greatest extent practicable," and might even be changed at a later time. A significant addition was a patient "freedom of choice" provision: network area designation did not require patients to seek care in the area in which they resided, nor did it preclude patient choice of physicians or facilities in another network or physician referral of patients to another network.

For each network, the Secretary was to approve a Network Coordinating Council when 75 percent of the facilities had designated representatives. The initial functions of an NCC were electing an executive committee, listing member facilities and representatives, appointing a medical review board, obtaining facility agreements to participate, developing a plan for relating to adjacent NCCs, and establishing relations with all HSAs and PSROs intersecting the network. Ongoing functions involved preparing a written plan, submitting an annual report, monitoring the medical review board, and maintaining working relations with HSAs and PSROs.

¹⁴¹ Federal Register 22502, June 3, 1976, "Conditions for Coverage of Suppliers of End-Stage Renal Disease Services."

A Medical Review Board of no more than seven members was to be established, including an internist engaged in ESRD care, a renal transplant surgeon, a qualified nurse, a qualified social worker, and up to three additional physicians providing ESRD care. MRB members could not review cases in which they had any "professional involvement," or facilities in which they had any "direct or indirect" financial interest. The MRB was to develop ways to monitor the effectiveness of the patient long-term program, oversee evaluation of the comparative performance of physicians, nonphysicians, and facilities, coordinate the medical care evaluation studies of network facilities, provide written recommendations to physicians and facilities about possible improvements in the care of patients, and report annually to the NCC and the Secretary.

The NCC was to develop "written working arrangements" with those areawide HSAs and State Health Coordinating Councils wholly or partially within the network area, indicating how it intended to integrate its planning responsibilities with these authorities. In similar fashion, the MRB was to develop written arrangements with the intersecting PSRO areas describing how it would integrate its medical review responsibilities with those of the PSROs. The NCCs and MRBs were obliged to accept continuing responsibility for planning and medical review as requested by HSAs and PSROs.

Minimum utilization rates for ESRD facilities were published for unconditional, conditional, and exception status, and are summarized in Table 13. *Exception* status might be granted under "unusual circumstances" on a time-limited basis, possibly to be renewed annually "under circumstances where rigid application of minimal utilization

Performance evaluations were to be "based on aggregate data concerning patterns of care in relation to both normative data from the medical information system and criteria and standards developed by the network for at least the following areas of patient care: appropriateness of patients for the proposed treatment procedures, mortality, and morbidity."

²The minimum requirement was for one medical care evaluation study annually for each facility.

Table 13

MINIMUM UTILIZATION RATES REQUIRED OF ESRD FACILITIES

	Facility Status	
Facility Type	Unconditional Certification Requirements	Conditional Certification Requirements
Transplant center	15 or more trans- plants performed annually	7 to 14 transplants performed annually
Out-patient dialysis facilities: ^a		
Urban ^b	6 or more dialysis stations, with an average of 4.5 or more dialyses per station a week	6 or more stations, with average of 4-4.5 dialyses per station a week
Rural ^b	3 or more stations, with average of 4 dialyses per station a week	2 stations, with average of 4 or more dialyses per station a week
In-patient dialysis facilities ^a	3 or more stations, with average of 4 or more dialyses per station a week	2 stations, with average of 4 dialyses per station a week

SOURCE: 41 Federal Register 22514-22515, June 3, 1976.

^aOut-patient facilities are those performing more than 20 percent of their dialysis treatments on an out-patient basis; in-patient facilities are those performing 20 percent or fewer treatments on an out-patient basis.

^bA facility is considered urban if it is located in an SMSA of 500,000 or more population; rural facilities are located in SMSAs of less than 500,000 or are not included in an SMSA.

rate requirements would adversely affect the achievement of ESRD Program objectives."

The long-term organizational issues were finally settled fully three years after the ESRD Program became operational. Or were they?

FUNDING THE NETWORKS

BQA recognized in 1974 that ESRD networks would require federal government financing. In October, Goran noted in a letter to the Region IV Regional Health Administrator that a BQA request to HSA for additional funds for the first phase of network identification had not been answered. So individual RMP organizations across the country were providing travel funds and Goran hoped that additional RMP and CHP cooperation might enable the preliminary identification to be completed.

The political problem for BQA became more acute as network organizational activity got under way in response to the final policies. In February 1975, the Regional Health Administrator for Region VI sent Goran a letter from Dr. A. R. Remmers who was actively organizing a Texas network, asking about the administrative costs of organization. Goran responded that no decision had been made about the mechanism for network funding, but that several options were being considered.

In April, the possibilities included funding networks either through a PHS line item, or through a Medicare facility reimbursement

¹Memorandum from Director, BQA, to Regional Health Administrator, Region IV, "Resources for the Establishment of End-Stage Renal Disease (ESRD) Networks," October 21, 1974.

²Memorandum from Regional Health Administrator, Region VI, to Director, Bureau of Quality Assurance, "Administrative Costs in Administering ESRD Network Activities," February 27, 1975.

Memorandum from Director, BQA, to Regional Health Administrator, Region VI, "Administrative Costs in Administering End-Stage Renal Disease (ESRD) Network Activities," April 3, 1975.

mechanism. By September, the first option had been changed to "'front end' funding through the contract mechanism," with the source unspecified. The funding issue languished temporarily after publication of the NPRM, though many public comments were received on the failure of the proposed regulations to address the funding issue.

In early 1976, HSA Administrator van Hoek raised the issue with Assistant Secretary Cooper in connection with proposed publication of a second NPRM. He wrote: ³

As you review the regulations, however, it is important to recognize that no funds are currently identified to support the operation of NCCs and MRBs or to continue support of the ESRD MIS [Medical Information System]. Prior to publication of this NPRM, therefore, it is essential that the resources necessary to permit both the creation of MRBs and NCCs and continued operation of the ESRD MIS be made available. To publish the NPRM prior to the identification of such resources would foster expectations in the medical community which the Department is not, at the moment, able to fulfill.

If funding for the networks was not forthcoming, van Hoek recommended that networks be deleted from the regulation and replaced by more limited mechanisms for medical review and facility planning.

The decision to publish final regulations triggered an apparent resolution of the issue. A mid-March meeting was held in the office of Under Secretary Lynch. Assistant Secretary Cooper, SSA Commissioner Cardwell, and BHI Director Tierney, arrived at an "in principle"

Memorandum from Acting Administrator, HSA, to Deputy Associate Commissioner for Management and Administration, SSA, "Funds and Positions Necessary to Finance End-Stage Renal Disease Networks Through a Contract Mechanism," April 9, 1975.

²Letter from Thomas G. Murray, M.D., Acting Chief, End-Stage Renal Disease Branch, BQA, to Richard J. Glassock, M.D., Harbor General Hospital, Los Angeles, September 12, 1975.

Memorandum from Acting Administrator, HSA, to the Assistant Secretary for Health, "End-Stage Renal Disease (ESRD) Notice of Proposed Rule Making (NPRM) - Funding of Network Coordinating Councils (NCC) and Medical Review Boards (MRBs) and the ESRD Medical Information System (MIS) - ACTION," January 28, 1976.

agreement that SSA would finance the development and operation of NCCs and MRBs "through the Medicare facilities reimbursement mechanism."

The agreement was only a first step toward resolution. The exact mechanism then became the basic question. BQA staff favored a "lead facility" concept whereby a single ESRD facility would administer the network for other facilities. But this proposal generated substantial opposition from ESRD facilities: they supported the network concept, although few were prepared to relinquish network administrative authority to another institution. The medical community preferred a "pass through" mechanism (an independent organization). In August 1976, Goran summarized views about the pass-through approach: 1

We understand that BHI has concerns about both the legality and desirability of this approach. In addition, we feel that it has the potential for inhibiting required network relationships with HSAs and PSROs. Nevertheless, we believe it is necessary to recognize and address the concerns of the ESRD community to the maximum extent possible in accordance with requirements for efficient program operations. Therefore, we request that you explore the possibility of a pass-through approach.

The bureaucratic delay was obviously a direct result of the divided views in the medical community.

The issue of "lead facility" versus "pass through" simmered for several months. By spring 1977, however, the decision was reached to permit both funding procedures. The first approach proposed having one ESRD facility as a network administrative center to perform administrative functions on behalf of the network. The second approach also proposed one facility, but its function was to establish, under agreement, an independent organization to perform administrative functions. The decision to fund networks by both procedures was

¹ Memorandum from Director, BQA, to Director, Bureau of Health Insurance, SSA, "Reimbursement of ESRD Network Operating Costs," August 10, 1976.

incorporated into a document issued on August 29, 1977, which was then sent to facilities, regional offices, and intermediaries. Fully fifteen months had elapsed since publication of the final regulations, and more than four years since the ESRD program had become operational.

POLICY PLANNING AND IMPLEMENTATION: A SECOND LOOK

We conclude this section with some observation on the policy planning experience of the long-term program. First, the policy underlying the long-term program did not guide planning as clearly as did that for the interim program. While the overall objectives of the ESRD program were relatively clear, those of the long-term program were far less so. Congress required minimum utilization rates and medical review and HEW necessarily accepted these without challenge. But ambiguity surrounded the meaning, significance, and feasibility of these functions, and was a continuing source of problems.

Second, though means-ends relationships were fairly straightforward for the interim program, they were much less clear for the
long-term program. Access to care, for instance, resulted from a
universal benefit, terminal patients seeking treatment, and physicians
able and willing to provide it; the added contribution of networks was
never analyzed. Cost control was driven primarily by the facility
reimbursement screen, which was a powerful incentive to high utilization; what further incentive could a minimum utilization rate add?
Quality of care was to be insured by medical review; but questions
about the feasibility of improving quality this way persisted
throughout the planning effort. In short, causal relationships between ends and means were believed to exist for the long-term program,
but such beliefs were never subjected to careful analysis. Questions
of need, feasibility, and simple alternatives were never systematically
addressed.

Medicare Bureau, Health Care Financing Administration, End-Stage Renal Disease Networks Funding Policies and Procedures, August 29, 1977, distributed by I.L. 77-30(A), September 1977.

Third, the network strategy revealed some serious problems in the regionalization of health services. It was based as much on an ideological commitment of HEW and the medical community to organize the medical delivery system as it was on proven models and persuasive supporting data. In fact, no models existed for organizing the major urban centers having several important medical centers, or for accommodating state renal programs, and none were suitable for scaling up from simple regional activity to complex national effort. Data were consistently discovered to be poor and normally reflected the bias that guided their collection. The criteria for network designation were inconsistent in both concept and application. And HEW demonstrated an inability to coordinate the design of three regional programs--ESRD, health planning, and PSRO--that it was developing simultaneously. Overall, the need for coordination among institutions beyond that required by simple affiliation agreements was alleged but never demonstrated.

Fourth, unlike the interim program planning period, there was no deadline for the long-term planning effort. The pace of the four-year effort, consequently, was determined partly by the public notice and comment requirements of the Administrative Procedures Act, partly by conflict between the government and the medical community, partly by internal bureaucratic conflict, and partly by divisions within the medical community.

Finally, planning was complicated by the existing administrative system, which included many organizations and lengthy formal and informal clearance processes offering repeated opportunity for bureaucratic conflict. The complexity of this system, and its recurring internal conflict, moreover, created great frustration within the medical community as it sought to deal with the government, frustration reinforced by the absence of formal consultative mechanisms.

VII. PLANNING AN ESRD MEDICAL INFORMATION SYSTEM

ORIGINS

At the outset of the ESRD program, two registries existed for end-stage renal disease patients. The National Dialysis Registry was operated by the Research Triangle Institute, located in Research Triangle Park, North Carolina, under contract to the National Institutes of Health. The Human Renal Transplant Registry was maintained by the American College of Surgeons, Chicago, also under contract to the NIH. It was assumed that the ESRD program would take over responsibility for both registries, merging them in a single system. This quite reasonable expectation proved to be extremely difficult.

The SSA data needs for the ESRD program were related mainly to reimbursement and relied primarily upon the existing Medicare claims processing system. During 1973, SSA initiated the development of a system to generate data, for July through December 1973, on characteristics of the enrolled patient population, utilization of program services, and utilization of physician and other medical services; ESRD facility characteristics were not to be included initially. Within SSA, the system was jointly developed by BHI, the SSA's Office of the Actuary, and SSA's Division of Health Insurance Studies in the Office of Research and Statistics. It was intended to be used for administration and research, and the intended users were to be SSA organizations in Baltimore. Based on the Medicare claims processing system, which was adapted to the needs of the ESRD program, the initial system was to provide "minimal, essential data" for internal SSA purposes.

The format for the 1973 program statistics was specified in Memorandum from Aaron Krute, Deputy Director, Division of Health Insurance Studies, Office of Research and Statistics, to Addressees, "Chronic Renal Disease Program Statistics: Revised Tabulations," November 5, 1973; Memorandum from Aaron Krute to Addressees, "Chronic Renal Disease Program Statistics--Table Revisions," January 16, 1974; and Memorandum from Aaron Krute to Addressees, "Chronic Renal Disease Program Statistics, Part III: Revised Tabulations on Utilization of Physicians' and Other Medical Services," February 28, 1974.

The distinction between a "management" information system for reimbursement purposes and a "medical" information system for broader purposes emerged relatively quickly, but the purposes and nature of the latter came to be understood far more slowly. BHI had examined both the dialysis and transplant registries and regarded them as inadequate for administrative purposes. The medical community also considered them as deficient for simple counting of patients and facilities and certainly for clinical management of patients. The ESRD "Medical Information System" (MIS), then, came to mean the data system needed to support networks, medical review, calculation of minimum utilization rates, and high level administrative needs of the program.

Concern for a medical information system was explicit, for instance, in the NKF White Paper of April 1973, which assumed a three-tiered system of users: kidney disease transplant and dialysis center review boards, regional review boards, and a national review board. The lowest level required "a clinical and laboratory data base for all patients admitted to the transplantation-dialysis program." The regional level called for "a record system of all patients on dialysis and transplantation in the region," including a current computer listing of all those awaiting a cadaver transplant that would facilitate the best possible match between available kidneys and waiting patients. And the "national review board" was to establish and maintain a patient registry of all patients with end-stage kidney disease; it would track the status of each patient as he or she progressed through either dialysis or transplant treatment.

The White Paper reflected many of the problems that government officials would face in seeking to create an ESRD MIS. First, the data system was inferred from the expected organization of the ESRD program. Second, though support for medical review and transplantation were specifically identified functions, the objectives of the

¹National Kidney Foundation, White Paper: Guidelines for the Implementation of Public Law 92-603, Title II, Section 299I, Concerned with Chronic Renal Disease, April 1973.

system were not clear. Third, a comprehensive computer system was envisioned that would produce timely data and serve multiple users. Finally, MIS recommendations were not accompanied by a cost analysis, a cost-benefit analysis, or a cost-effectiveness analysis, and basic questions of system feasibility were never examined. All these problems impaired the government's attempts to establish MIS.

DESIGN

BQA was preoccupied in 1973 with writing exceptions criteria and procedures for facility certification. Soon after Dr. Alvin Goodman became head of the ESRD unit in January 1974, however, he took action to create an ESRD MIS. In February, he recruited Richard Godmere from BQA's Division of Program Appraisal and Data Planning to design a renal data system. Godmere was then responsible for developing relationships between the PSRO data effort and existing Medicare and Medicaid data systems, and had previously designed the Medicaid MIS.

Policy authority for the ESRD MIS came in the final policies:²

A data system will be developed for monitoring patient care, and participation by each facility in a prospective patient care transplant registry and a dialysis and transplant outcome registry will be required.

This statement established the basis for action, as it did for the entire long-term program.

Although Godmere had no previous experience with end-stage renal disease, he saw the information system as a challenge and opportunity. It was, he said, "ideal from a systems standpoint." A closed system could be created to handle the expected maximum of 70,000 patients. Individuals would be entered into the information system when treatment began and the entry would terminate when death

¹The acting division director then was Royal Crystal, later head of the BQA ESRD unit.

²Final Policies, April 17, 1974.

occurred. "A total systems approach," in Godmere's view, "was the way to go." Unfortunately, the problem would prove far more difficult than expected.

Godmere's basic strategy was to develop a package of data requirements materials, secure reactions from an advisory committee, revise the package on the basis of these comments, and return it to the advisers. He sought (1) to control the design work as much as possible, (2) to avoid consulting the medical community unless it was necessary, and (3) to lay out requirements in such detail that the government could contract for a data processing operation. Difficulties were encountered at each of these steps.

In the first issue, the MIS design was complicated by the interaction of policy and technical questions. The role of medical review boards was unresolved, which created a dilemma. If MRBs were to function effectively, they would need supporting data. But such data could be collected only after the purpose of MRBs was clearly stated. And this did not occur until the final regulations of June 3, 1976, were published.

The second issue, consultation with the medical community, also posed difficulties. An ad hoc steering group was formed representing both transplantation and dialysis physicians. These meetings were held with this group in 1974 from March through June. The documentation for the first meeting listed three ambitious general objectives for the MIS: to support implementation of Section 299I (ESRD program) and 249F (PSRO program) of P.L. 92-603; to contribute to "better patient management, utilization, quality control and overall

¹Personal interview with Richard O. Godmere, February 28, 1978.

²Transplant surgeons included Drs. J. Wesley Alexander, Folkert O. Belzer, John J. Bergan, H. M. Lee, Anthony P. Monaco, and Ben A. VanderWerf; Drs. William E. Braun and Bernard Amos were also included later. Nephrologists included Drs. Christopher R. Blagg, John D. Bower, Richard J. Glassock, John H. Sadler, and Fred L. Shapiro.

medical care appraisal"; and "to consolidate within a single, economical computer-based system a nation-wide dialysis and transplant registry responsive to the needs of practitioners, institutions, and government alike." Two subsystems were proposed: a transplant and dialysis patient registry and a tissue-typing and organ procurement system. Nine "specific objectives" were stated; four of these illustrated the complexity being sought:

- 3-3. Program for automatic comparison of patient record and services rendered with explicit criteria developed by the professional community to determine on an exception basis (a) the appropriateness of level of care, (b) appropriateness of services rendered in relation to patient needs, and (c) other utilization and patient factors.

 3-4. Establish a medical data base which describes medically and demographically the transplantation and chronic dialysis population, and that can fulfill related research objectives for clinical, epidemiological and health services research.
- 3-5. Measure the morbidity, mortality, and duration of in-hospital confinement of transplantation and chronic dialysis patients.
- 3-6. Measure the degree to which transplantation and chronic dialysis patients are rehabilitated medically and vocationally.

This statement reveals both a fundamental reliance upon "the professional community" for criteria of judgment, and also a comprehensive approach to the data problem.

An ESRD organizational system was anticipated that included local medical review boards, regional boards, and a national ESRD advisory committee to the PSRO council. It assumed phasing out of the two NIH-funded registries by July 1, 1975, the continuation of existing tissue-typing and organ procurement systems, and the cessation of flow of ESRD data to the SSA--"particularly with the area of

¹Memorandum from Dick Godmere, System Project Manager, to Steering Group for the End-Stage Renal Disease Information System, "General Agenda and Enclosures for Meeting to be held on March 27-28, Holiday Inn, Bethesda, Maryland," March 21, 1974; with enclosures.

population, demographic and possible utilization statistics." The overall plan envisioned a "modular" design for flexibility, a "report writer" for nonrecurring report requests, and computer capability to accommodate a growing patient load. The documentation listed the output reports produced and the data elements used by seven existing renal data systems. 1

These ambitious plans precipitated controversy among the medical consultants. One group, including Blagg and Sadler, favored minimal collection of data. The process of patient treatment could be tracked, they said, but few inferences about outcome and quality of care could be drawn from such data. The other view, expressed by Glassock and Shapiro, favored the collection of more data on disease entities for use in medical review of provider facilities, especially morbidity indicators of mortality.

Materials produced for the second meeting reflected the discussion at the first meeting. Objectives were revised modestly; reference to two major subsystems was eliminated; and the term "specific objectives" was changed to "major functions." All references to network, regional, and national review boards were purged from these materials. Data collection requirements and proposed reports were generally more modest than what had been originally projected. On the other hand, the function of the prospective transplant registry was now also to serve "as a central national listing source for potential organ transfer." "Inputs" were reduced to four major

¹The seven systems were SSA, ACS/NIH Transplant Registry, RTI/NIH National Dialysis Registry, California (RMP) CRD Patient Information System, New York Department of Health/Kidney Disease Institute, Hennepin County Kidney Center, and University of Cincinnati.

Memorandum from Richard O. Godmere to Steering Group for End-Stage Renal Disease Medical Information System, "May 15, 16, 1974 Meeting," May 10, 1974; with enclosures.

³This expanded view was from Goodman and Godmere. The transplant community was divided among those favoring use of kidneys by a single center and those who supported sharing of kidneys on a regional basis. Few favored national sharing arrangements.

categories: initial medical history; major status changes; follow-up; and prospective transplant listings. Eleven "output reports" were identified, including patient population characteristics, patient flow, institutional activity, and local MRB activity.

This process resulted in a systems specification document prepared by Godmere after the third consultants' meeting and before a meeting of an advisory committee to the ESRD unit of BQA. This document listed five "principal objectives": to help local MRBs monitor medical care and utilization, to assist improvement of patient management by facilities and local MRBs, to assure participation by facilities and patients in a prospective transplant registry, to assure participation of facilities and patients in a dialysis and transplant outcome registry, and "to enable concerned organizational elements at local, regional and national levels to assess and evaluate ESRD care delivery and impact of the [ESRD] amendment." Multiple uses remained central to the ESRD MIS.

On organizational matters, it was recommended that only the dialysis and transplant outcome registries would be merged into the single national system. Systems for tissue typing, organ procurement, and prospective matching of transplant recipients would continue on a regional basis, except that the national system would coordinate these regional systems and maintain an up-to-date national listing of patients. Also, the MIS was to operate independently of the SSA claims processing system, except for common use of certain input forms. Physician compliance in submitting the patient history form was to be secured, as part of the patient eligibility process, by requiring its inclusion with the medical evidence form submitted to the SSA district office.

Systems Specification, End-Stage Renal Disease National Registry Information System, Bureau of Quality Assurance, June 1974.

²This latter group met on August 8 and 9, 1974, in Rockville. Sadler was the only member of both the MIS steering group and the program advisory committee.

The rationale for this coordination role was "to assure that all prospective transplant candidates are listed in these regional registries."

Buried on pages 29 and 30 of the document was the clearest description of the ESRD MIS and its purposes:

The system is structured to gather and measure ESRD patient care delivery from entry of the patient into end-stage renal disease condition (Medicare program) through care and movement of the patient in the therapy process to outcomes.

In short, each patient would be tracked through all discrete stages of treatment by a system that would then "produce timely, consistent, orderly and accurate results."

Sadler, in a letter to BQA, commented on the revised system specifications that came from the August 8 and 9 meeting. Regarding the revised patient history form, he wrote: "I have serious reservations about the validity and usefulness of much of this data, but on the whole these are the data which must be collected to satisfy requirements. I think this is the best form we are likely to get it into at this time. If experience shows it is not valuable, surely we will still be able to change the system rationally." Wistfully, he commented about the entire system: "I think we must all recognize that physicians involved in the care of dialysis and transplant patients will object to these forms. Those who are experienced with prior forms will object less since these are indeed an improvement. If we are to have an information system, I think these queries coupled with the billing statements cannot be practically reduced much further."

In the fall and winter of 1974, the MIS design effort was moving toward a contract award in 1975, reinforced by NIH's announced intention to terminate its financial support for the dialysis registry in

The ad hoc steering group was divided on the question of whether to collect data on patient rehabilitation. It was torn between the desire to do so annually and serious questions about the validity of such data given the self-interest of either physicians or patients completing the forms.

²Letter from John H. Sadler, M.D., to Thomas Murray, M.D., September 11, 1974.

February 1975 and the transplant registry at the end of June. An ESRD program-supported MIS had logic in its own rights, but it also offered financial relief to NIH. As the months of 1974 slipped away, however, BQA realized that even a mid-1975 contract award would leave the government many months short of an operational information system. Consequently, the HSA administrator wrote the Deputy Assistant Secretary for health at the end of 1974, recommending the extension of NIH funding of the two registries. The situation was reviewed, NIH was asked to continue its support for the registries, and it did so.

In early 1975, a BQA pretest of ESRD MIS forms was conducted in California and Mississippi. In California, a Kidney Disease Information System, established in 1972 by the California Regional Medical Program, was threatened with termination because of the national phase-out of RMPS activity. The system, considered one of the best statewide systems in the country, was temporarily saved by Goodman's intervention with the RMPS. An agreement was reached in October 1974 whereby the RMPS released \$153,000 of California RMP money which, with \$41,000 from the California Department of Health, was to be used by the state kidney data system to pretest the ESRD MIS forms. Mississippi was selected as a second test site because it had a strong statewide ESRD delivery system, the result of mid-1960s PHS support and subsequent Mississippi RMP funding.

The director of the California kidney data system, Marina Mann, was responsible for running the pretest, assisted in California by Dr. Richard J. Glassock, chairman of the state RMP ESRD advisory committee, and in Mississippi by Dr. John D. Bower, of the University

¹Memorandum from Administrator, HSA, to Deputy Assistant Secretary for Health, "Continued Funding for National Institutes of Health (NIH) Kidney Dialysis and Transplantation Registries," September 30, 1974.

²Memorandum from Program Coordinator, End-Stage Renal Disease Program, Division of Peer Review, BQA, to Acting Chief, Operations and Management, Division of Regional Medical Programs, "California RMP: Project #86B - Kidney Disease Information and Evaluation System," September 5, 1974; and "Memorandum of Understanding between California Regional Medical Program and the Bureau of Quality Assurance, Health Services Administration," September 26, 1974 and October 10, 1974.

of Mississippi Medical Center. In California, participating facilities were selected by early March, given an initial briefing on April 4, and trained on April 22 and 24. In Mississippi, the initial briefing and training session occurred on April 29. The sixty-day pretest took place in both states in May and June 1975.

The pretest was reviewed in California on July 11 and in Mississippi three days later. Various problems with the forms were identified: "data loss" occurred because of the number of institutions involved with a single patient; "data not collected" revealed deficiencies in forms; multiple forms were used for certain purposes; inappropriate forms for others. The general problem of data quality was highlighted: though designed to monitor quality of care, it was concluded that the system "will provide only general data and not be useful as a quality measure." Institutional problems with submitting data were a serious concern. The report on the California review observed:

Billing clerks cannot properly complete the inpatient form because such things as reason for admission are medical facts. Clerks usually approach items from the standpoint of justifying length of stay rather than describing the patient's condition. In addition, the real reason for admission might not be known until discharge, after some evaluation of condition occurs.

And the Mississippi review produced this judgment:

Persons completing bills do not have medical records expertise. They will consciously or unconsciously complete forms in a manner which will insure payment, even if, medically, the facts are not entirely correct.

The implications for the validity of the data were serious. Compliance was a central unresolved concern. California reviewers felt that

^{1&}quot;Report of Meeting with Representatives of Providers on the ESRD Registry Pilot Test--San Francisco, California, July 11, 1973," Matt Plonski, n.d.; and "Report of Meeting with Representatives of Providers on the ESRD Registry Pilot Test--Jackson, Mississippi, July 14, 1975," Matt Plonski, n.d.

the system had to be tied to the bill payment process to insure compliance, while Mississippi observers arrived at the opposite conclusion. The results were far from encouraging.

Meanwhile, BQA was taking the necessary steps to secure, under contract, a data system manager. The decision to seek an outside contractor, rather than build on internal HEW capability, had been an early one. The alleged advantages of a contractor over a government organization were the former's ability to assemble the required personnel faster and with less difficulty, its flexibility of operations, and the ease with which the government could fix management responsibility.

Uncertainty about funding the MIS delayed issuance of an RFP and the contract award. Goodman, in October 1974, wrote Goran that an ESRD MIS contract had first priority among potential fiscal 1975 contracts and would absorb the "greater portion" of the \$500,000 requested by ESRD for all contracts. By February 1975, it was estimated that \$380,000 was needed immediately to contract for an MIS with a July 1 starting date, and that an additional \$325,000 was needed for fiscal 1976 operations. It was requested that "H evaluation funds" be used for the MIS: its purpose was clearly evaluative, and such activities were "classically" an H responsibility.

Funds for the contract, however, came mainly from SSA, not the health arm of HEW, a result of the complicated relationship between BQA and BHI. In late January 1975, Goran wrote to the BHI director, reviewing the results of numerous meetings between their respective staffs. He suggested specific changes in supplementary forms

¹Memorandum from Program Coordinator, End-Stage Renal Disease Program, to Director, BQA, "F.Y. 75 Contract Plans," October 17, 1974.

²Draft Memorandum from Acting Administrator, HSA, to Director, Office of Policy Development and Planning, H, "Funding of End-Stage Renal Disease Medical Information System," February 21, 1975.

³Memorandum from Director, BQA, to Director, Bureau of Health Insurance, SSA, "Results of Interagency Coordination in the Development of the End-Stage Renal Disease Medical Information System (ESRD MIS)," January 31, 1975.

SSA-2742, "Medicare Chronic Renal Disease Patient History," and SSA-2743, "Medicare Chronic Renal Disease Charge and Service Information," and in the process for submitting them; he also suggested the appropriate organizational relationships between the BQA-managed MIS, BHI, and SSA's Office of Research and Statistics. BHI was expected to print and distribute the revised forms, notify intermediaries of new procedures, and change the necessary keying instructions and computer programs, while BQA would pretest the forms, prepare instructional materials, and conduct training sessions around the country. The request for approval of the proposed modifications contained no request for funding assistance. In mid-April, the HSA administrator sought formal approval from SSA for Goran's proposed modifications, so that a request for proposals (RFP) could be issued to prospective bidders. If no comments were received by April 21, HSA would assume no problems existed and would issue the RFP.

Tierney finally responded to Goran in May, attributing his delay to the number of SSA components that had to approve the proposed modifications. He accepted the general approach developed by "our respective staffs" and agreed to the need for changing existing forms and procedures. He agreed that the general principle guiding the changes in processing forms should be the avoidance of duplication between the data needs of SSA and those of the MIS. "We have concluded," Tierney wrote, "that in order to avoid all but a very limited amount of duplicate processing, insure proper control over information that is critical to each organization, and satisfy the requirements for timeliness and completeness of data, the most suitable procedure would be to have our respective organizations receive, process, and retain only that information which is critical to our

¹Memorandum from Acting Administrator, HSA, to Assistant Commissioner for Administration, Social Security Administration, "End-Stage Renal Disease Medical Information System," April 15, 1975.

²Memorandum from Director, Bureau of Health Insurance, SSA, to Director, Bureau of Quality Assurance, HSA, "Request for Approval of Proposed Modifications to SSA Renal Disease Information and Bill Supplement Forms Necessary to Support the Implementation of the End-Stage Renal Disease Medical Information System," May 15, 1975.

respective systems and areas of responsibility." This would mean transferring to BQA the responsibility for form SSA-2742 and the proposed in-patient bill supplement form, and leaving the receipt and processing of the out-patient bill supplement for SSA. No reference was made to financing.

Within Health Services Administration, however, BQA was unable to secure the necessary funds in time to permit issuing an RFP. An "eleventh-hour" request to SSA resulted in the approval of \$220,000 from the Medicare Trust Fund for initial contract funding. Additional funds bringing the total to \$310,000 were found within HSA. The impotence of the BQA ESRD unit was fully revealed and the residual power of BHI clearly demonstrated.

BQA had published a request for "qualified sources" in the Commerce Business Daily in March, and seventeen organizations submitted statements of qualifications. A work group met on April 15 and evaluated these organizations. Six of the seventeen were eliminated from further competition because they scored below the 60 point cutoff, and eleven organizations were judged technically qualified to receive a RFP. After resolution of the funding issue, an RFP was issued in early May. Proposals were received one month later, and evaluated on June 4 through 6, 1975. A data processing firm in Alexandria, Virginia—Value Engineering, Inc.—was formally selected as the contractor for the ESRD MIS. 2

THE VALUE ENGINEERING CONTRACT

The Value Engineering contract ran from July 1, 1975, through spring 1978, when it was terminated. The lifetime of the contract is summarized in Table 14.

¹ Memorandum from Project Officer, BQA, to Contracts Operation Branch, HSA, "Review of Proposals for Advance Synopsis for HSA-240-SYN-8(B)," April 23, 1975.

²Value Engineering scored 60 points, below the ten other qualified sources in the April evaluation of its qualifications. The Research Triangle Institute scored highest among the sources.

Table 14

VALUE ENGINEERING CONTRACT FOR ESRD MIS

Phase	Effective Date	Expiration Date	Award
I	6-30-75	7-31-76	\$310,000
Extension		8-31-76	
II	9-1-76	12-31-77	595,000
Overrun	8-25-77		184,000
Extension	1-1-78	3-31-78	199,000

During this contract, numerous problems were experienced. Recurring design problems were encountered with input forms, expected outputs, and processing of data. Merging data from SSA, the dialysis registry, and the transplant registry posed difficulties. The capability of the contractors, the management of the contract by BQA, and the relations of the contractor with SSA/BHI were the source of continuous complications. The expected operational starting date was continually slipped. The initial reports were not generated until Phase II of the contract. Successive funding decisions required new consideration of the choice among three alternatives: renewing the contract, issuing another RFP on which Value Engineering would not be permitted to bid, or transferring the ESRD MIS to BHI.

The design problems stemmed from several sources. Godmere's legacy was that of a one-man operation which left many uninformed about basic system design. One problem flowed from the decision to design the MIS within BQA and sign a contract with a data processing firm rather than a systems design/software firm. His successor complained about the output tables: "There were cross tabulations. These were marked as tables, but they were shells and included no dummy data. There were reams of potential outputs that were nothing more than shells of tables. There was no understanding of whether

the system could produce this data or these outputs. What operations were needed to insure that entry onto tape or disc would lead to data getting to a particular cell in a given table was not known. There was no algorithm or there were no algorithms." Other problems derived from the difficulty in fixing input requirements. Modification of forms specifying inputs continued throughout the entire Phase I contract and into Phase II.

The system for submitting data, especially medical information, was especially vexing on the issue of compliance. Initially, both BQA and BHI agreed that ESRD facilities should submit all MIS data forms directly to the MIS data center. But, as the expected implementation date drew nearer, both agencies heard from physicians that compliance with the request for filling out the forms completely and accurately would be low unless the forms were an integral part of the reimbursement system. BHI estimated, however, that tying the forms to the bill processing system would lengthen the data processing time by about three months.

In mid-February 1976, therefore, BQA changed its position, now favoring submission of data forms by facilities to intermediaries, and then by intermediaries to the MIS data center. BHI responded that compliance would indeed be low if not tied to reimbursement, but noted that compliance problems would not be overcome simply by the reimbursement link. Reimbursement affected facilities, not physicians, and the latter were essential for completing the in-patient

¹Interview with Ronald Gold, February 24, 1978.

These views were set forth in a Draft Memorandum from Director, BQA, to Director, Bureau of Health Insurance, SSA, "Implementation of the End-Stage Renal Disease (ESRD) Medical Information System (MIS) - ACTION," prepared on February 5, 1976, but not sent; the contents of this memorandum were communicated to BHI at a February 20 meeting.

Memorandum from Director of Special Operations, BHI, to Director, Division of Peer Review, BQA, "Role of Medicare Intermediaries in Data Gathering for the ESRD Medical Information System (MIS)," February 25, 1976.

medical information supplement. The out-patient supplement and the patient history form, on the other hand, could be easily processed by the existing billing system. Regardless of the approach adopted, BHI predicted an impact on Medicare claims processing procedures and their costs. In processing medical information, BHI said, "we are going to experience problems in the areas of facility compliance and more importantly by the community of ESRD facilities."

The ESRD MIS project officer wrote to BQA in May 1976, indicating that a compromise had been worked out for data collection that included both specific data elements and the paper flow from the ESRD facility to the BQA processing center. The compromise was designed to tradeoff compliance, timeliness, and accuracy of reporting. A patient history form and an out-patient service form would be sent by the facility to the intermediary, then to SSA, and then to the BQA processing center. There would be no separate in-patient medical form, but medical data would be abstracted by the MIS from a billing form assessing in-patient morbidity and mortality; other procedural modifications were indicated. Although the content had changed, plans for annual surveys of facilities, transplant patients, home dialysis patients, and rehabilitation remained unchanged.

In the following month, Marina Mann, the initial Technical Director of the Value Engineering project, wrote a scathing critique of the MIS system, which she said was "currently laden with serious problems." The decision to link the information system to the billing system had numerous deficiencies: neither SSA nor the intermediaries would refuse to pay a bill if data forms were incomplete; an artificial relationship between a facility's medical personnel and its billing

¹Identical letters were sent on by Ron Gold, Project Officer, BQA, to Thomas G. Murray, M.D., Acting Chief, End-Stage Renal Disease Branch, BQA, and Mr. Phil Jos, Division of Special Operations, BHI, May 10, 1976.

²Mann, the former director of the California RMP kidney data system, had become Value Engineering's Technical Director for the ESRD MIS in October 1975, as a result of a BQA recommendation. She resigned from Value in May 1976 and wrote her untitled critique to a BQA physician adviser in June.

personnel was being forced, which would probably affect the quality of data; the physical result would be monthly submissions by 800 facilities, totaling 300,000 data forms annually to monitor 30,000 people; problems would exist regarding who had authority to require data submission, whether SSA, BQA, intermediaries, or the contractor; and the lag time between initial data submission and receipt by BQA would be substantial and depend on facility billing time, and the respective processing times of the intermediary, SSA, and the contractor. The six-page, single-spaced critique concluded by recommending removal of the data system from the billing system, linking data submission to annual facility certification, reducing seven input forms to one, and using the NIH computer facility. But Mann, who had left Value Engineering and was then consulting to BQA, though highly regarded in the medical community, was never again in a position to exert much influence on developments.

The contract with Value Engineering was reviewed for sole source renewal in late spring 1976. Although the review committee judged the proposal "for the most part responsive to the RFP," it criticized the contractor for failing "to link staffing, work to be performed, and budget." Indeed, Mann was still identified as Technical Director, and there was no mention of a replacement. No timetable was provided for beginning national operations by October 1, 1976. The dependency of the contractor on SSA and the intermediaries was not addressed in sufficient detail, the review group continued, and the proposal "showed that the contractor had failed to understand "the relationship of the fiscal intermediary in the Medicare program." It was judged "totally inadequate" on data verification, and it failed to address the deliverables required under the original contract.

A resubmission of the Value Engineering proposal was requested, and a one-month extension of Phase I granted. But given internal HEW

¹Memorandum from Ron Gold, Project Officer, BQA, to James C. Zeglin, "Technical Evaluation of Contractor's Proposal (HSA 240-BQA-417 (6) JCZ)," June 1, 1976.

difficulties in securing authority for a competitive RFP, in addition to those of rebidding the contract and the strong BQA desire to get an operational system in place, a decision was reached to renew the contract.

Reports finally began to be produced under Phase II of the contract. A two-track system--facilities and patients--had been agreed upon, and a report on facilities as of June 30, 1976, was released in April 1977, followed by another facility report late in that year. Patient information as of December 31, 1976, was not released until early 1978. A spring 1978 report by Value Engineering summarized the process:

Over the history of the ESRD MIS a great deal of time has been devoted to the design and development of format and content of output reports. There have been many iterations of some of these designs and many different groups of advisors and consultants have contributed their ideas. However, this process has, in many cases, led the design concept in a full circle and taken a great amount of time. Alternative approaches that provide for more rapid implementation should receive serious consideration for the future. As reports are circulated among user groups, the comments both favorable and unfavorable that are received will provide most of the guidance needed for further planning.

¹End-Stage Renal Disease Medical Information System, Facility Report No. 1, Medicare Approved ESRD Suppliers, June 30, 1976, Series 1 - The Nation Reported by Network, Department of Health, Education, and Welfare, Health Care Financing Administration, n.d.

²Facility Report No. 2, Medicare Approved ESRD Suppliers, December 31, 1976, Series 1 - The Nation Reported by Network, DHEW, HCFA, n.d.

³ESRD MIS, Profile of the ESRD Patient Population, December 31, 1976, Series 1 - The Nation Reported by Network, DHEW, HCFA, n.d.; and ESRD MIS, Distribution of ESRD Dialysis Patients and Facilities, December 31, 1976, The Nation Reported by Size Categories of the Standard Metropolitan Statistical Areas, DHEW, HCFA, n.d.

⁴Value Engineering Company, End-Stage Renal Disease Medical Information Systems: Report for the Period, September 1, 1976-March 24, 1978, Contract Number HSA-240-75-0123, March 1978.

By then, however, the time for further planning had almost expired.

CONTRACT TERMINATION AND SYSTEM TRANSFER

In May 1977, the new Secretary of HEW, Joseph Califano, announced the creation of the Health Care Financing Administration. HCFA removed BHI from SSA and Medicaid from the Social and Rehabilitation Service, each intact, but with the long-range objective of merging the two major health financing programs of the federal government.

The creation of HCFA brought the renal program under one administrative agency: BHI was renamed the Medicare Bureau, and the CRD group remained essentially in place; BQA, however, was removed from the Public Health Service and brought into the new agency as the Health Standards and Quality Bureau (HSQB) along with its ESRD unit.

Funding problems for the ESRD MIS arose in spring 1977 and led to a request for funds from the Medicare Bureau. Money was now a problem wholly internal to HCFA, and it was requested that consideration be given to consolidating the Medicare CRD data system and the ESRD MIS. In June, a HCFA task force concluded that a basis for integration existed. The recommendations were for the establishment of a CRD Management Information System, including both financial and medical data, creation of a joint work group to develop the integrated system, and joint operation of the system. The rationale was that similarities existed between the two systems, that 80 percent of the MIS inputs would come from the Medicare system, and that the MIS had a history of numerous problems. The ESRD MIS was too ambitious, made continuous design changes, added new inputs before outputs were delivered, and depended on a contractor with limited design capabilities. HSQB (previously BQA) had maintained no consistent design specifications, had been reluctant to fix them, and had used up money without achieving outputs.

¹Interview with John C. Parmigiani and Alan Heller, Baltimore, Maryland, February 2, 1978.

²Memorandum from John C. Parmigiani to Addressees, "Integration of the CRD and ESRD Systems - INFORMATION," June 21, 1977.

A complex struggle then ensued, which lasted approximately six months. There were interventions from the physician community, mostly in support of a separate ESRD MIS. The data processing issue was broadened to a question of ESRD consolidation within HCFA, a much more highly charged issue. On the information system, however, a HCFA decision was reached in early 1978 to terminate the contract with Value Engineering and transfer the internal administrative responsibility from HSQB to the CRD group within Medicare Bureau.

In mid-1979, HCFA published the first series of regular reports from the ESRD MIS. These were distributed in the fall to facilities and networks. Reactions to these reports ranged from appreciation that data were now beginning to flow to criticism of the quality to some efforts to organize data collection at the network level. The future of the MIS remains unclear, however, because HCFA, in mid-1979, was undergoing substantial reorganization to consolidate the Medicare and Medicaid operations. Although the Medicare Bureau was reorganized out of existence, the CRD group retained responsibility for the ESRD program. But some program personnel, including those responsible for the MIS, were transferred elsewhere in HCFA, thus further complicating the prospects for a good data system.

SUMMARY

What observations can be made about the MIS experience? First, at no time in the design, development, or operation of the system was sustained, informed policy direction given to the system. Consequently, issues of feasibility, need, and cost either went unanalyzed or were poorly investigated. Although Goodman initiated the effort, he paid relatively little attention to it. And neither Murray nor Crystal, his successors, had sufficient authority or power to give policy leadership. Within H, neither Klar nor anyone else exercised

This followed from the general consolidation decision; see Memorandum from Administrator, Health Care Financing Administration, to All HCFA Components, "Consolidation of the End-Stage Renal Disease Program into the Medicare Bureau -- ACTION," January 17, 1978.

responsibility for the MIS. And it is unclear whether BHI, basically kept out of the process until 1978, would have provided much policy attention to it. The ESRD MIS was never significant to higher level officials.

One suspects the existence of a general problem, namely, that effective data systems are of limited concern to public policy officials. The incentives governing their behavior lead them to grapple with topical policy issues, not with the details of operational matters. Private firm executives, by contrast, behave quite differently. Because information is a primary means for controlling organizations, information systems receive from them sustained attention, guidance, and discipline. Either control is such a remote possibility for public officials, or their personal rewards are so detached from organizational performance, that information systems receive from them scant attention.

A second observation is that several critical assumptions in the design stage were the source of subsequent problems for the MIS. It was assumed, for instance, that a comprehensive system, including a large number of data elements, was both feasible and needed, and was required immediately. Fixation on processing capabilities of high-speed computers led to expectations about high performance of the system, without analysis of more critical problems, like those of securing high quality data inputs. Furthermore, familiar problems of the existing Medicare system nourished a belief that a new system could be created which would avoid these problems and that awarding an external contract was the means to this end. It was also assumed that a multiple-user system was both feasible and necessary, that real-time data transmission was essential, and that time lags of several months were unacceptable. The natural experiment from 1974 to mid-1979 "tested" these assumptions and found them wanting.

Third, it was not well understood that the administrative location of the MIS would be a source of continuing problems. But no practical interest in the system was shown within H, no financial support was found in HSA, and no design and management capability was established by BQA. Difficulties were then compounded by relying for

MIS management upon a contractor organization having no previous ESRD experience, limited design capability, poor proximity to the Baltimore-based Medicare data system, and very little understanding of the relations among physicians, facilities, intermediaries, and BHI.

Fourth, fixing early on a single design, rather than vigorously exploring various design alternatives, made little practical sense. A sequential development of a system rather than an immediate complete development and a simple universal system augmented by selective probability sampling surveys were alternative strategies never considered. Nor did the consultative processes of the relying upon an "expert" committee provide the basis for a thorough critique of the system design.

VIII. CRAWLING THROUGH THE GEARWORKS

Implementation demands our attention because it cannot be assumed today that federal policies will be faithfully translated into desired program outputs. Indeed, contemporary cynicism holds that government can do nothing well. But cynicism is an impoverished response to the basic issue of the government's competence to implement policy, and ignoring the implementation issue is no less bankrupt. Understanding implementation is a prerequisite to improved performance. Or, in medical terms, diagnosis must precede prescription and treatment.

A mechanical metaphor serves better than a medical one, however. This study of the End-Stage Renal Disease program can be compared to a lengthy, detailed inspection of a factory. During this inspection, the abstract model of a factory as an organization transforming inputs to outputs has been substantially enriched by an appreciation for its internal complexity and its numerous connections with the external environment. In this section, we summarize what we have learned from our crawl through the gearworks of the ESRD program.

In many ways, the ESRD program has been a success story.

Congress established this Medicare program to pay for the treatment of individuals with kidney failure. As a result, patients are receiving care, bills are being paid, and access to treatment is no longer an issue. Although program costs are of continuing policy concern, aspects of the cost control experience have been encouraging. There is, furthermore, no reason to believe that quality of care has declined during the program, even though the patient population now includes more elderly and sicker patients. In certain respects, however, the success of this program should not be surprising: A relatively small number of patients are treated by fewer physicians in even fewer facilities and the government is paying the bill.

It is also worth noting that important innovations have been introduced by the program. The screen on facility reimbursement created strong incentives for efficiency in delivering outpatient maintenance dialysis. The reimbursement of physicians, either through

treatment facilities or directly by the monthly capitation method, departs from traditional fee-for-service reimbursement. De facto mandatory assignment, moreover, effectively prevents facilities from billing patients for more than Medicare's allowable deductible and copayment amounts. Finally, the facility certification process permits the number and capacity of treatment facilities to increase in reasonable relation to growth in the patient population.

Notwithstanding its accomplishments and innovations, the ESRD program cannot be regarded as a model of successful implementation. The question is, why? Two explanations suggest themselves: expectations were unrealistically high; or performance was below average.

Expectations of the medical community may have been high initially because few nephrologists and transplant surgeons had experience with Medicare but had dealt mainly with the quite different National Institutes of Health. But after five years of experience with the program, the medical community remained disgruntled with the disparity between actual program performance and what it deems to be reasonable.

Performance, of course, is judged in many ways even though few good measures of it exist. But a review of the complexity of the implementation experience can make possible a qualitative assessment of performance; it can identify sources of implementation problems, suggest remedies, and draw lessons for the future and for other programs. This chapter constitutes such a review.

THE STATUTE AND THE CONGRESS

The legislative history of Section 299I was so brief that knowledge of this far-reaching legislation was extremely limited within the Congress, the public, the press, and even the medical community. The absence of hearings left numerous issues unresolved, with which the bureaucracy would later contend. The introduction of the amendment at the end of the 1972 Congressional session caught the Bureau of Health Insurance by surprise, and greatly compressed the time for it to understand the disease, its treatment, and the implications for Medicare. Only the timely inclusion by Senator Long of the "charges"

related to cost" statement in the final Senate debate was of subsequent aid to BHI in its development of reimbursement policy. A more deliberate legislative process surely would have clarified some of the key uncertainties and might well have aided implementation.

Section 299I, however, did convey the basic intent of Congress:
Medicare was to pay treatment costs for those with kidney failure.
Entitlement criteria were explicit for dialysis patients, less so for transplant patients. But great authority was delegated to the HEW Secretary on all other matters. It was assumed that BHI would exercise de facto discretion for the Secretary, certainly on reimbursement issues.

The silence of the statute on home dialysis, however, meant that reimbursement policy was constrained by the regulations and policies for durable medical equipment, which introduced financial disincentives for this treatment form. This silence on home dialysis also limited BHI's discretion and required further legislation to change policy.

Section 299I required medical review and minimum utilization rates, but gave no indication of what these requirements meant, how the required efforts would be funded, or who would administer them. Nor did the legislation require that ESRD networks should be established, let alone financed by Medicare trust funds. In short, the statute was explicit only on a few matters, was unclear about others, and delegated substantial authority to the Secretary.

Public Law 95-292, enacted in 1978, had a legislative history which began in 1975. This legislation, far more detailed than Section 299I, sought to arrest and reverse the decline in the proportion of home dialysis patients, though the statute was much weaker than the earlier legislative proposals. The 1978 law was relatively clear about home dialysis reimbursement, but somewhat ambiguous regarding facility reimbursement. Existing policy about physician reimbursement and ESRD networks was incorporated into statutory form, which thus ratified earlier administrative actions.

Both the legislative history and specific language of a statute affect its implementation. Hearings can clarify key issues, permit

the bureaucracy time to anticipate implementation requirements, and generate consensus about legislative intent. Statements by floor managers can critically augment the language of a statute. Statutory language can be directive about matters whose meaning is clear and about which prescription or proscription are necessary. But such language often delegates substantial authority to administrative discretion. This delegation occurs when general intent is understood but detailed guidance can only occur in implementation, when legislative time is scarce, when there is legislative confidence in the likely administering agency and substantial uncertainty about both ends and means.

Legislation, therefore, can authorize, finance, motivate, channel, and constrain implementation behavior, but it cannot prescribe such behavior in detail nor can its implementation effects be easily predicted. Furthermore, since explicit provision for legislative oversight is seldom made for new programs, Congressional follow-up of legislation is a very uncertain process. But regular oversight hearings, annually or biennially, do represent one potential means by which Congress can exert more continuing and constructive influence over implementation.

THE ADMINISTRATIVE SYSTEM OF IMPLEMENTATION

The administrative system of the ESRD program consists of three elements—a policy system, an infrastructure linking policy and delivery, and a system for delivery of care.

The Policy System

Statutory authority for the ESRD program is formally vested in the HEW Secretary, but there are so many demands on the Secretary's time that delegation of authority is required. A prominent feature of the ESRD policy system has been the scramble to determine who, how, and to what ends Secretarial authority should be exercised.

At the time P.L. 92-603 was passed, the strongest Office of the Secretary policy role in health financing was played by the Deputy Assistant Secretary for Planning and Evaluation (ASPE). The Office

of Assistant Secretary for Health played an important, but lesser, role. But ASPE/Health was preoccupied with proposed legislation for extending health insurance coverage, and policy planning for implementing the ESRD program went largely unnoticed.

ESRD policy planning did engage the Office of the Assistant Secretary for Health, and especially Dr. Ronald Klar. Although neither Assistant Secretaries Charles Edwards nor Theodore Cooper defined a department-wide policy planning strategy for existing health financing programs, both supported Klar's ESRD activity. But Klar appeared to view BHI as an adversary, both in bureaucratic jurisdiction and in conception of policy. He seemed to regard policy as Secretarial pronouncements resulting from discrete decisions, and showed little concern for policy resulting from continuous interaction with operations. Moreover, Klar believed that once policy was stated, others were responsible for its execution. Consequently, little or no effort was made by Klar to create an oversight mechanism for the program in the Office of the Secretary, nor to build strong internal or external support for ESRD policies. Finally, though Klar was involved until early 1978, he was not followed by a successor interested in the ESRD program's implementation.

BHI viewed policy planning as the elaboration of Congressional intent within the framework of the Medicare statute as expressed in regulations. For the first two years of the ESRD program, the BHI Deputy Director for Program Policy, Irwin Wolkstein, played a central role in all policy issues. In addition, a renal policy group was created in BHI and the Chronic Renal Disease branch; though primarily operations, it also dealt with policy. In time, however, the BHI policy resources diminished substantially. None of Wolkstein's successors expressed the same degree of interest in the ESRD program. The closest approximation came after the Health Care Financing Administration was created: Eugene Rubel, first as Assistant to the Deputy Administrator and then as head of the Office of Special Programs, began to exercise ESRD policy leadership, but for little more than a year. The BHI renal policy group, moreover, was decimated by retirement and reorganization in 1978 and 1979. Consequently, policy

responsibility for the ESRD program floated steadily downward to the CRD branch without sustained guidance by any long-tenured, knowledgeable senior official in either HCFA or the Office of the Secretary.

The ESRD unit in the Bureau of Quality Assurance had important policy responsibility for minimum utilization rates, medical review, networks, and data. This unit played a relatively weak policy role, however; it had limited access to the Secretary, minimal support from the Assistant Secretary for Health, few bureaucratic resources, and no capacity to exercise genuine leadership of the medical community. Of its four directors, only Dr. Alvin Goodman possessed the status and force of personality to influence policy significantly. BHI sometimes displayed passive cooperation, and sometimes passive aggression toward the BQA ESRD unit. It seldom actively supported BQA. It acquiesced, for instance, in the Public Health Service deference to expert medical opinion on the poorly developed network concept. The BQA ESRD unit was decimated after the creation of HCFA, then later reconstituted.

The policy system for the ESRD program, in short, has been fragmented between its Washington and Baltimore components, whose relations have often been competitive, certainly far from cooperative, and unstable over time. An adequate policy system functioned initially in a tolerable manner, but declined in capability over time. Personnel turnover in HCFA and HEW and the bureaucratic reorganization of HCFA have further weakened the policy system. The result has been weak policy control over operations, confusion in the operational domain, and confusion among those who are delivering care. This situation can be remedied only by action of the Secretary taken in conjunction with the HCFA administrator.

The Administrative Infrastructure

The ESRD administrative infrastructure connects the policy system with the system for delivery of care. In particular, it

includes the organizational elements and procedural relationships for patient eligibility and entitlement; claims processing for reimbursement of physicians, facilities, and home dialysis patients; facility certification; networks; and the medical information system.

Patient eligibility and entitlement are established by statute, require minimal interpretation, and are easily administered on a decentralized basis.

Claims processing requires clearly stated reimbursement policies that are administered on a decentralized basis by established institutions, and are responsive to strong demand for high performance by physicians and facilities. Political conflict focuses mainly on policy determinations and, to a lesser extent, on efficiency of operations.

Facility certification is a traditional Medicare function, modified for nontraditional institutions and with a mix of old and new procedures. It depends upon central policy guidance and decentralized administration. The basic policy issue for the federal government is how to permit treatment capacity to grow in relation to a growing patient population and, perhaps, how to constrain the growth of institutional capacity to encourage home dialysis. Views about the quality of the certification function vary within the medical community according to the outcomes of particular decisions.

These functions—patient entitlement, claims processing, and facility certification—can be administered by the infrastructure in an acceptable manner once the basic policies have been clearly stated. Questions of administrative efficiency will remain, but these are different than questions of direction or of choice of means.

ESRD networks, however, are characterized by ambiguity of purpose and questions of feasibility of means; for example, there remain substantial doubts about the medical review process to measurably improve the quality of patient care. Implementation problems will arise from varying expectations about purpose and performance and from political conflict among institutions in a network area, including the health planning agencies and Professional Standards Review Organizations.

The medical information system is characterized by ambivalence about use and users, and an unduly complicated mix of centralization and decentralization in design and operation. It is a new data function grafted onto the existing Medicare data system. Conflict exists about purpose, quality, and timeliness of data. The absence of high-level policy control over system design and operation has been a continuing source of implementation problems. Whether these problems will be resolved within the next few years or whether the system will continue to manifest chronic instability remains to be seen.

The performance of the administrative infrastructure depends greatly upon its relations with the policy system. Traditional health financing functions, like claims processing administered by existing institutions, tend to run themselves once policy is established. But new functions—like network organization, medical review, and the data system, which combine ambiguity of purpose, decentralized implementation, and substantial conflict—do not work automatically. If these functions are to be adequately fulfilled, they require that the policy system provide continuing guidance and direction and assistance in the resolution of conflict.

The Delivery System

The organizational base of the ESRD program is the delivery system, which consists of treatment institutions and the health professionals who run them. The key to overall system performance lies in the physicians and nurses who run treatment institutions.

Nephrologists and transplant surgeons are both very highly trained medical specialty groups. They administer patient care, supervise the operation of treatment institutions, and integrate these activities with the administrative infrastructure of the program. Head nurses are critical to day-to-day management of patients and treatment facilities.

The success of the ESRD program largely depends on the competence and the professional capability of the physicians and nurses at the base of the system. Where clear policy exists, where the

Medicare administrative procedures are more traditional than new, those factors combined with competent professionals administering basically routine therapy on a daily basis essentially guarantee the delivery of high quality care.

Problems at the delivery system level arise from two sources. First, differences of opinion exist within the medical community about the relative desirability of transplantation versus dialysis, center dialysis versus home dialysis, dialysis reimbursement rates for different institutional settings, the function of networks, and the kind of data to be collected. These different viewpoints are fed back to the policy system directly and quickly. The inability of the policy system to resolve conflict leads to continuing policy confusion and conflict or capture of program activity by one or another faction within the medical community.

Second, physicians become the spokesmen for patients. This occurs because the ESRD program administrators find it much easier to deal with the smaller number of physicians and facilities than the larger number of patients, because physicians have a monopoly of knowledge about all aspects of system performance, and because of traditional physician preferences to represent the interest of This traditional role of patient representation is underpatients. standable and desirable in most cases. But patients suffering from end-stage renal disease, whether treated by dialysis or transplantation, become far more knowledgeable about their disease and its treatment than do patients suffering from acute medical problems. The government, however, has not recognized the patient population as an important information resource about the performance of the ESRD program. On matters like quality of care, for instance, where policy and infrastructure problems are likely to persist for some time, where the prospects for measuring and affecting the quality of care through medical review are relatively low, and where the associated administrative costs are perhaps prohibitively high, systematic access by the government to patient opinion could be useful. But the development of patient-access mechanisms requires an explicit policy commitment and a strong policy system to supervise implementation.

THE IMPLEMENTATION PROCESS

The legislative stage of policy formulation strongly influences implementation, as discussed above. And Congress is often hasty or even careless in its attention to the implications of legislation for implementation. But even the most reflective legislators cannot anticipate all consequences of their actions; the clearest of legislative intentions contain ambiguities; and the most carefully drafted statutes delegate substantial authority to administrators. The exercise of administrative discretion is required at the successive phases of implementation, and this discretion results in a number of problems.

Policy Planning

Policy planning restates and extends statutory language in the concrete terms of regulations and directives in order to establish the policy framework for operations. Three types of policy planning can be identified from the ESRD program experience: time-constrained planning between the enactment of a law and its effective date, as was true for the interim program; open-ended planning, as was the case for the long-term program; and apparent time-constrained planning, like that required for implementation of P.L. 95-292. The difference between the first and third types is whether a genuine need exists for an operational response: an interim program response was needed because terminal patients became eligible for benefits on July 1, 1973, and severe consequences would follow a failure to meet that deadline. If no real costs will be sustained from delay, however, and the former policies can be continued without disruptive effects, statutory time requirements provide weak stimuli to policy planning.

There are various general constraints on policy planning—time, the continuity of the new with the old, the bureaucracy's perception of the problem, the availability of data, and the constellation of political forces acting on the policy planning effort. The interim program was time—constrained by the brief legislative history of

Section 299I, by the eight months between its enactment and its effective date, and by the known severe consequences of failure to create an operational program by July 1, 1973. Discontinuity also constrained policy planning: the requirements for implementing Section 299I departed sharply from those of traditional Medicare, and BHI had little knowledge of or experience with end-stage renal disease. But internal BHI opinion was divided on whether to respond to the new requirements of the kidney provision or try to adapt the program to existing procedures; those perceiving a need for new requirements prevailed. Data on reimbursement was scarce, of poor quality, and varied greatly across the country. The pattern of political stakeholders had not yet been established, however, so the reimbursement screen was created with relatively no opposition, a partial benefit derived from the limited planning time for a new program.

Policy planning for the long-term program, by contrast, was subject to few time constraints. The proposed policy of networks was sufficiently complex, differences within the government sufficiently deep, and data sufficiently limited in availability and quality, so that the policy planning process was protracted over three full years. Differences within the government, between the government and the medical community, and within the medical community complicated the network planning.

Several agencies are usually involved in policy planning, so the existence beforehand of a functioning policy system, embracing both department and agency interests, can greatly aid the policy planning effort; the absence of such an arrangement can equally hinder it. Such a system existed to some degree for the interim program, helped by a strong initial capacity in BHI; it evolved further during planning for the long-term program; and then deteriorated after the creation of HCFA (at least during the period of this research).

Operational Planning

Operational planning transforms policies into detailed guidance about particular administrative routines and tasks. It includes the

design, development, and publication of forms, data collection instruments, and manuals, as well as the specification of the concrete procedures for their use. Ideally, it also includes the development of materials for teaching administrators how to use new procedures, as well as the conduct of the related instructional programs.

Operational planning before the effective date of a new program is essential to insure that an acceptable transition to operations takes place. But this study has revealed operational planning to be an extremely weak link in implementation and a source of numerous problems. Most of the available planning time before issuance of the interim regulations was absorbed by policy planning, because administrators were unable to resolve critical policy issues until they stood in the shadow of the July 1, 1973 deadline. Consequently, operational planning was severely time-constrained. It could not parallel policy planning to any great extent, especially because the concrete problems of operational planning were contingent upon policy planning decisions. The initial intermediary letter, for example, could not be written before agreement on the interim regulations was established.

The consequence of this time squeeze on operational planning is that many important operational problems are not resolved until the initial period of operations. For the ESRD program, this meant that important claims-processing problems existed when the program became operational and persisted for months thereafter. Serious cash-flow problems arose, which imposed financial burdens on physicians, providers and facilities, suppliers, and even patients. Had adequate attention been paid to the need for educating SSA regional and district office personnel, intermediaries, hospital and facility administrators, and physicians, these cash-flow problems might have been mitigated to a large extent. Apart from the unfairness of such burdens, there were political costs to the government stemming from these cash-flow problems. Constituents of the ESRD program became angry at early administrative inefficiencies, and partly for this reason, forced modification of existing physician reimbursement policies and the design of the ESRD medical information system. Thus, inadequate operational planning may constrain policy options in undesirable ways, may unnecessarily create adversary relationships between the government and the medical community, and may create an image of administrative incompetence that is hard to eliminate once acquired.

Must operational planning inevitably be subject to the severe time constraints that insure start-up operational problems? In a private organization, two factors work to secure and protect adequate time for operational planning. First, the effective date of a new program is calculated in relation to the total planning time required, including that needed for operational planning. The effective date is not set by an arbitrary, essentially political or legislative determination. Second, policy planning is largely administrative, without the political character of public programs. So more time is allowed for planning, including operational planning. The challenge to government administrators is to provide adequate planning time for new programs within a set of political constraints. Congress may wish to consider oversight hearings at some point before the effective date of a program to insure time for adequate operational planning.

Start-Up Operations

Two types of problems exist for the start-up phase of operations. Inadequate operational planning has already been discussed. The other problem is that new programs experience a step-function increase, or surge, in demands placed upon the administrative system that overwhelms its capacity to respond. In the ESRD program, this surge was followed by confusion and turbulence, initiation of emergency procedures, a gradual resolution of key problems, and the eventual arrival at an equilibrium.

Administrative resources are often inadequate at the beginning of a new program. One missing resource in the ESRD case was an instructional program for explaining the new program to those outside Washington who would be administering it. Another resource limit was the ratio of administrators to work load, which was adverse

at the start. Work load surged initially, then moved toward a gradual equilibrium, while the development of administrative capability and the acquisition of personnel was more gradual, without regard to this initial surge, and perhaps constrained by personnel ceilings of the federal government.

Minimizing start-up problems requires planning before operations begin, developing and initiating an instructional program for administrators, and augmenting administrative resources to respond to the surge in demand without overstaffing for the future. The value of such action, of course, depends upon its estimated political, economic, and administrative benefits compared to the estimated costs of not doing so.

Learning by Doing

As experience with program operations develops, lessons will be drawn and needs perceived for modifying policy. A rational model of learning evokes the image of a spacecraft moving toward a known objective along a preset trajectory, to which precise mid-course corrections are made on the basis of feedback about the divergence between the actual and the required pathway to the objective.

A more political view of learning, however, recognizes that actual operations not only represent movement toward an objective but also create a pattern of interests having diverse preferences about organization, procedure, and outcome. Preexisting but unrecognized constraints, as well as newly created ones, come into focus. The implementing organization discovers increasing interdependence with other agencies and the corresponding diversity of views about how to deal with it. Examples include the BHI negotiations with the Veterans Administration, the intersection of network design with health planning concerns, and the internal tension within BQA between ESRD and PSRO priorities. Differences within the medical community also became sharper, as in the case of center versus home dialysis. Furthermore, varying interactions between different parts of the bureaucracy and different segments of the medical community produce an increasingly complicated distribution of political opinions,

interests, and resources. Learning then becomes an accommodation of purposeful program activity to differences within the bureaucracy, within the medical community, and between the two.

Modifying policy during operations can sometimes be done solely within the bureaucracy. But it is difficult for the bureaucracy to set deadlines, even harder to keep them, and the forces for delay are often greater than those favoring action. Policy change requiring new legislation also requires a long period of time and activates many political forces. Conflict occurs over the desirability of action and over the possible outcomes.

Some policies will assuredly lead to litigation or the threat of it. Policy changes may seek to avoid litigation, as was partly true for the modification of physician reimbursement policy in 1974, or respond to court action, as occurred with the issuance of reimbursement regulations in the wake of the 1976 D.C. District Court and 1977 D.C. Circuit Court decisions. It is a small point, but for health financing programs litigation will be used to determine the rights and authorities of government and affected parties, and thus it needs to be explicitly recognized as important to the implementation process.

One overall conclusion is obvious: the pace and quality of learning by doing depend greatly on the competence of the policy system and its capacity to deal with political conflict. Some portions of programs continue almost automatically after initial policy has been set; they rely upon routine administration and competent performance by service delivery professionals. But for those aspects of implementation that require continuous policy adaptation to new demands—that is, require learning by doing—a strong policy system is essential.

THE SUBSTANCE OF THE ESRD PROGRAM

The substance of implementation involves translating desired policy objectives into actual delivery system outputs through predictable administrative routines. Problems arise from the limited ability of administrators to predict more than a few relevant relationships, or to predict the interactive effects among many elements

in a complex system, as well as from the political constraints on learning. A few of the more salient examples from the ESRD program are illustrated here.

The Interim Program

Reimbursement issues raised numerous problems for implementation. Facility reimbursement, for instance, depended on the recognition that the ESRD program had eliminated the non-Medicare market as a basis for setting reimbursement rates, that a screen made good policy and administrative sense, and that the specific level of the screen was basically a reasonable estimate. It was also essential to recognize that reimbursement of outpatient dialysis treatment would decisively alter relations between hospital and nonhospital treatment settings. In retrospect, it is tempting to think that policy had to develop along these lines, though support for alternative policies existed at every juncture within the government and medical community.

Physician reimbursement policy was developed with data that indicated incredible diversity of practice across the country. Little information existed about how much physician time was actually needed to supervise the dialysis patient. Fee-for-service was undesirable and in the spring of 1973 capitation was politically unacceptable. So a policy of reimbursement through facilities was established, consistent with practice in many academic medical centers. Explanatory language, however, was inflammatory, and the diversity within the medical community was underestimated. Time, negotiation, and the threat of litigation changed the acceptability of capitation by the spring of 1974.

The negative effects of reimbursement policy for home dialysis were not clearly perceived in early 1973, though they were recognized soon after the interim regulations. Minor modifications were made administratively. But removal of the major, inadvertently created financial disincentives to home treatment required legislation. The five years from the interim regulations to the 1978 legislation revealed deep ambivalence toward home dialysis among administrators, legislators, physicians, and patients that was manifested in sharp political conflict at every stage of the process.

Reimbursement issues are at the heart of health financing programs. These issues are highly complex and, because the outcomes of policy decisions are so significant, intense conflict surrounds them. Initial policy sets the controls that govern for relatively long periods of time, partly because this policy creates vested interests that then set political limits on learning from experience. High-level competence is required to articulate policies consistent with Congressional intent and the general public interest, both in the early policy planning and in later policy modifications.

The Long-Term Program

The ESRD program is noteworthy because efforts were made to organize the delivery system as well as reimburse for services. Networks were the primary manifestation of this organizational impulse. Policy was developed mainly within the Office of the Assistant Secretary for Health and BQA, partly because the historic division of labor in health financing programs between reimbursement and "medical" issues and partly because of deep beliefs among government health professionals that organization was both needed and feasible. These views were held by many in academic medicine who believed that regionalization of ESRD services was necessary, that the ideal model of a stratified system of care emanating from a tertiary center was feasible, and that existing regional models provided a basis for scaling up to a national system.

Design criteria for the network system, however, were numerous, lacked internal consistency, and were inconsistently applied. Supporting data were suggestive but far from definitive at best; at worst, they were poor or nonexistent. Although relations between proposed ESRD networks and other regional entities—like Health System Agencies and PSROs—were addressed in the late stages of regulation writing, this did not prevent the creation of three distinctly different regional administrative systems. States were essentially ignored as logical administrative bases in favor of medical referral patterns, and the reimbursement implications (for copayment) of a state—based system were not given serious attention. Finally, the administrative agencies created to manage networks were

staffed by nonfederal employees, paid with federal funds, and dominated by the physician community.

The organizational impulse was also revealed in transplantation policy. Policy sought to restrict the number of certified transplant facilities on the assumption that the number of transplant operations performed by a center correlated with outcomes. But this assumption was not sustained by persuasive data. Consequently, the number of operations required for unconditional certification dropped steadily from 1973 discussions (50 transplants a year) to the 1975 proposed regulation (25 a year) to the 1976 final rule (15 a year) and the number of certified facilities rose accordingly.

In short, the organizational efforts were ambitious, less clear in purpose or concept than reimbursement policies, not well supported by data, and designed within the PHS, which exercised weak policy control over the outcome. It will take several years to judge the utility of the networks. And more rather than fewer transplant centers may turn out to encourage a greater number of transplant operations, a generally preferred policy outcome. The ESRD program provides little comfort to those who believe that the federal government can effectively organize the medical community by methods besides the reimbursement mechanism.

Data

The intelligent exercise of policy control depends, among other things, on the existence of good data. But the difficulties of developing adequate data systems are often overlooked. No one, for example, assumed that it would require five years to securely establish Medicare's authority to collect cost data for policy review purposes. Medicare's experience with hospitals caused people to think cost data would be easily available. The prospect of political conflict and the need for litigation was barely perceived, if at all.

Planning the ESRD Medical Information System reflected other problems. The initial design was overly ambitious in its degree of comprehensiveness and the volume of data that was to be processed. The MIS planning was quite unrealistic about serving multiple uses

and multiple users, and lacked a definite sense of minimal needs as a guide. Financial needs were never adequately estimated, with budget estimates being tailored to available resources without a corresponding reduction in aims; budgets, moreover, were always in question. The institutional strategy was also rife with difficulties: the decision to make versus the decision to buy resulted in an award to a weak contractor, supervised by weak management, lodged in the weakest organizational unit. Limited appreciation was demonstrated for the institutional complexity of the Medicare system, which was to be adapted for the MIS. Finally, the policy control over the system was weak to nonexistent; data systems apparently lie below the threshold of high-level policy attention.

LESSONS

The ESRD program is a health financing program that is as close to full federal funding as the United States is likely to come for some time. This single program has the objectives of providing access to care, containing costs, and insuring quality of care. What, then, are the primary lessons to be learned from this study of the program's implementation?

Access to life-saving care has been realized. This has resulted from near-universal financing, the demands of terminal patients seeking essential care, and the capacity and willingness of the medical community to provide such care.

Reimbursement for dialysis and transplantation services has been governed by a few key policy decisions made at the outset of the program and modified slowly over time. Complex as these policies are, they require relatively few administrative routines for their implementation. Demands for performance—primarily financial demands—are placed on the claims processing system by service providers. These factors practically guarantee an acceptable level of performance, though administrative efficiency can always be improved.

Cost containment is controlled by the incentives created by the reimbursement system. When incentives can be established administratively without immediate interference in the practice of medicine,

as they were for the screen on facility reimbursement, cost-control can be quite effective. A steady pattern of exceptions for higher cost treatment, however, will obviously weaken these effects over time. (Cost control incentives may diminish, however, if the facility reimbursement regulations implementing the 1978 legislation substitute greater administrative complexity for the relative simplicity of the screen and favor higher cost, hospital-based outpatient dialysis over treatment in nonhospital, limited-care facilities.) Where cost containment requires an explicit preference for one type of treatment, like home dialysis, policy will be harder to establish and its effects are more likely to be marginal. Overall, it is unclear whether pressures for cost containment can offset pressures that favor greater intensity of service in outpatient, maintenance dialysis.

Quality of care depends mainly on the competence of the medical community and the learning afforded by the regular provision of routine care to a large patient population. Whether formal medical review can improve the quality of care, by any measure of increased patient well-being, is an empirical question not likely to be answered for several years. There is not much likelihood of observing a positive effect of medical review. The effect of open-ended patient selection criteria, of course, means that the prospects for high-quality patient outcomes are diminished as the proportion of marginal patients is increased.

None of the outcomes of the ESRD program occur automatically. They result from policy decisions, whether arrived at consciously or inadvertently. One of the most distressing features of the ESRD program has been the gradual decline during the period studied of a policy capability, both in the Office of the Secretary and within HCFA. The ESRD program benefited from sound early policy decisions, especially on reimbursement. But subsequent policy guidance was ambivalent on both organizational and data issues to the program's detriment.

Indeed, for further extensions of health insurance coverage, this decline in policy capability is the most ominous implication of the ESRD experience. Perhaps future extensions of coverage will receive adequate policy attention during their implementation. But several things must take place for this to occur. First, policy must be understood as including legislation, Secretarial decisions and pronouncements, and the pattern of continuous agency decisions made in response to operational needs. Many of the health policy officials in the Office of the Secretary were preoccupied with health insurance legislation during the 1970s; the implementation of Section 299I was virtually ignored because of this fact. Some viewed policy as a matter of Secretarial pronouncement, assuming that others would carry out such statements. But effective implemention requires that legislation, Secretarial decisions, and agency decisions all be recognized as integral elements of policy and, further, that the constant communication of policy to the administrative and delivery systems is a task of high priority.

Second, if future health insurance extensions are to be effectively implemented, a department-wide policy capability must be established. In the Office of the Secretary, this capability should include representatives of both the Assistant Secretary for Health and the Assistant Secretary for Planning and Evaluation. It also requires a reimbursement-focused policy capability in HCFA. And these departmental and agency policy units must establish a continuous pattern of cooperative interaction. The idea is hardly novel, but the establishment of such a capability will require unambiguous and sustained support from the Secretary.

It may also be necessary to choose people for implementationoriented policy units who are different in training, experience, and
temperament from those involved in policy-as-legislation. The
latter tend to focus on the broad implications of choice at the
policy formulation stage, while the former need to be sensitive to
the policy implications arising from the details of the implementation process.

Finally, for the ESRD program and for extensions of health insurance coverage, Congress can play a critical role to insure the effective implementation of programs it authorizes through program oversight of two types. One type, seldom employed, is that of oversight hearings before the effective date of a program, perhaps two-thirds of the way between enactment and that date. Such a hearing might focus on the major policy planning issues resolved and outstanding and then emphasize the operational planning needs. The intent of such a hearing would be to accelerate resolution of policy issues and provide more time for the critical phase of operational planning.

The second type of oversight would be regular hearings, perhaps annually, to address issues of implementation. Such hearings might well consider the administrative system, the implementation process, and matters of substance. If the executive branch faced the prospect of an annual oversight hearing on program implementation, it might move with greater alacrity to resolve internal disputes. Annual hearings, moreover, might force agencies to address only the most critical issues and push them to do fewer things better.

Objections might be raised that both a departmental policy capability and a Congressional oversight function are unrealistic expectations. If so, it is equally unrealistic to expect effective implementation to occur. If the government accepts responsibilities of increased scope and complexity, as it has in the ESRD program, without checking the forces leading to diminished implementation capability and without providing strong policy guidance, performance can only suffer.

* * * * *

This report has analyzed the implementation of the ESRD program to mid-1978. Various changes have occurred in program management since then. In light of the conclusions of this report, these management changes and their effects also deserve assessment if we are to know how well the program is being implemented today.

Appendix A

PUBLIC LAW 92-603, 92ND CONGRESS, H.R. 1 OCTOBER 30, 1972

Chronic Renal Disease Considered to Constitute Disability

Sec. 299I. Effective with respect to services provided on and after July 1, 1973, section 226 of the Social Security Act (as amended by section 201(b)(5) of this Act) is amended by redesignating subsection (e) as subsection (f), and by inserting after subsection (d) the following new subsection:

- "(e) Notwithstanding the foregoing provisions of this section, every individual who---
 - "(1) has not attained the age of 65;
 - "(2) (A) is fully or currently insured (as such terms are defined in section 214 of this Act), or (B) is entitled to monthly insurance benefits under title II of this Act, or (C) is the spouse or dependent child (as defined in regulations) of an individual who is fully or currently insured, or (D) is the spouse or dependent child (as defined in regulations) of an individual entitled to monthly insurance benefits under title II of this Act; and

"(3) is medically determined to have chronic renal disease and who requires hemodialysis or renal transplantation for such disease;

shall be deemed to be disabled for purposes of coverage under parts A and B of Medicare subject to the deductible, premium, and copayment provisions of title XVIII.

- "(f) Medicare eligibility on the basis of chronic kidney failure shall begin with the third month after the month in which a course of renal dialysis is initiated and would end with the twelfth month after the month in which the person has a renal transplant or such course of dialysis is terminated.
- "(g) The Secretary is authorized to limit reimbursement under Medicare for kidney transplant and dialysis to kidney disease treatment centers which meet such requirements as he may by regulation prescribe: Provided, That such requirements must include at least requirements for a minimal utilization rate for covered procedures and for a medical review board to screen the appropriateness of patients for the proposed treatment procedures."

Appendix B ORGANIZATION

Chart No. 1. Social Security Administration

Chart No. 2. Bureau of Health Insurance

Chart No. 3. Health Services Administration

Chart No. 4. Bureau of Quality Assurance

These charts indicate the organization of the relevant federal government agencies during the years discussed in this report.

Chart No. 1 SOCIAL SECURITY ADMINISTRATION

(November 1975)

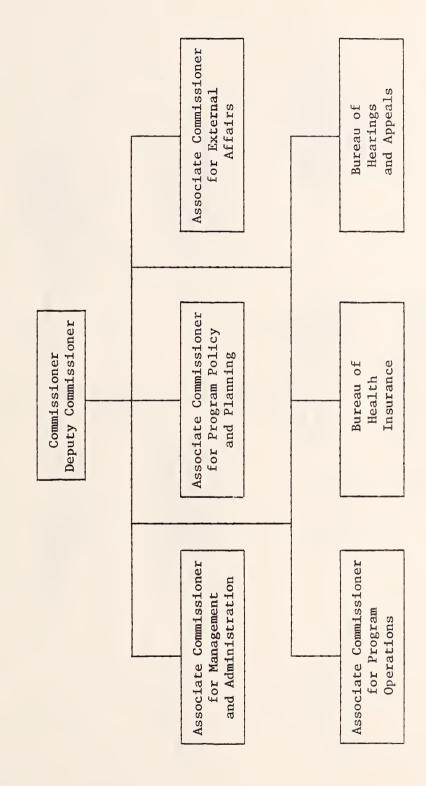
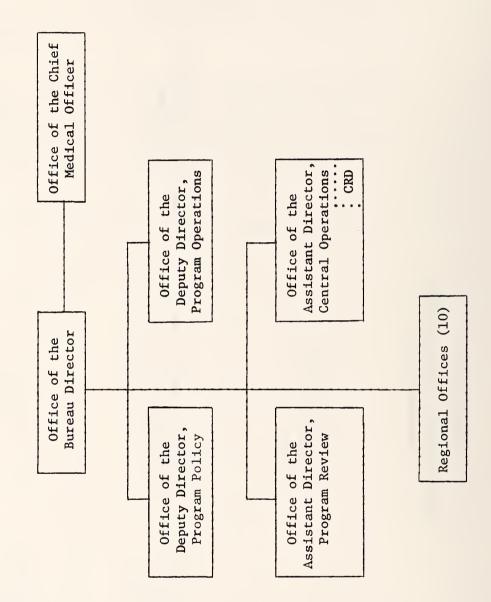
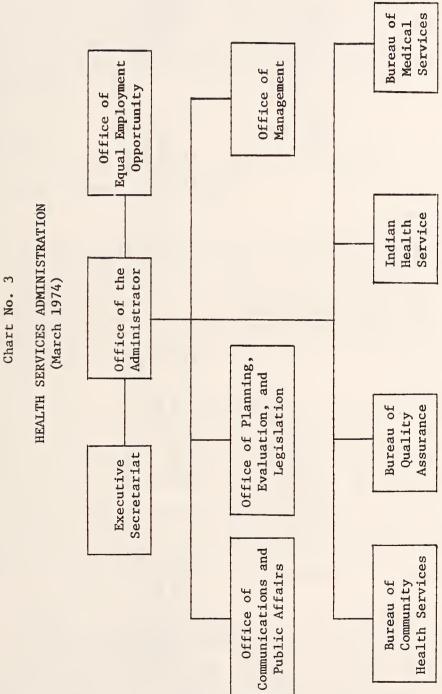


Chart No. 2

BUREAU OF HEALTH INSURANCE
(July 1976)





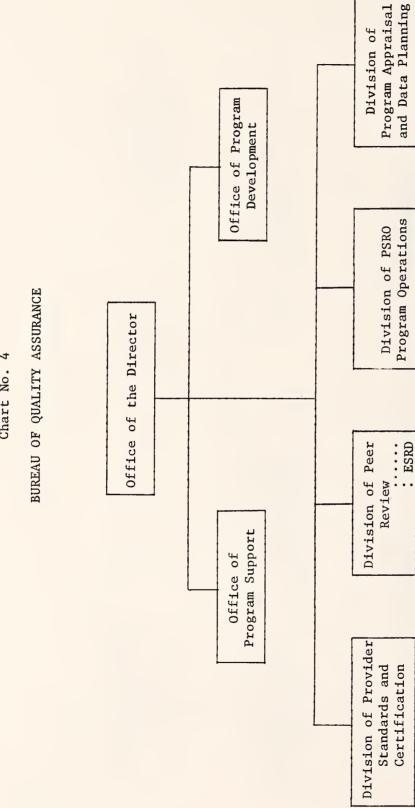


Chart No. 4

Appendix C NETWORK CONTROVERSIES

Two network designation controversies—New Jersey and Illinois—were summarized in Section VI. The more detailed analyses of these controversies are presented here. These accounts reveal some of the problems that occur whenever regionalization of health services is attempted.

NEW JERSEY

The preamble to the final regulations summarized the issue over the network status of New Jersey. $^{\!\! 1}$

A large number of comments on network area designations requested that New Jersey be designated as a separate, single Network. Data and information received subsequent to the publication of proposed regulations indicate a substantial reduction in the percentage of New Jersey patients being referred for treatment in out-of-state ESRD facilities. Therefore, the proposed network area No. 24 has been changed and New Jersey has been designated as Network No. 24.

The issue of whether to distribute New Jersey among two or three other networks or to treat it as a single statewide network first emerged in late 1974. In October, the consultants to Region II (New York, New Jersey, Puerto Rico, and the Virgin Islands) recommended that New Jersey be designated a single network, and the RHA later concurred. In Region III (Pennsylvania, Delaware, Maryland, Virginia, West Virginia, and Washington, D.C.), however, four meetings were held from mid-September through mid-October to designate

¹41 Federal Register 22502, June 3, 1976, "Conditions for Coverage of Suppliers of End-Stage Renal Disease (ESRD) Services."

²Memorandum from C. Robert Dean, M.D., Regional Health Administrator, Region II, to Michael J. Goran, M.D., Director, Bureau of Quality Assurance, "Networks for End-Stage Renal Disease (ESRD) Services," December 19, 1974.

networks within the region. The fourth, held on October 17 in the Philadelphia regional office, attended by 27 individuals, including four New Jersey representatives, considered the inclusion of the southern seven counties of New Jersey in a network with eastern Pennsylvania and Delaware.

New Jersey physicians were not unprepared for the raid from across the Delaware River. A statewide meeting of the New Jersey RMP Subcommittee on Hypertension and Renal Disease had endorsed a New Jersey network in early September. Dr. John P. Capelli, nephrology director at Our Lady of Lourdes Hospital in Camden, spokesman for the state effort, wrote the Philadelphia regional office before the October 17 meeting arguing for a single statewide network. New Jersey renal facilities had functioned as a network since 1969, he said, and patient care patterns reflected "the increasing utilization of all levels of ESRD care in New Jersey." Furthermore, statewide certificate-of-need existed and should not be disrupted, the proposed seven counties were a designated PSRO with no ties to Philadelphia, the state health planning agency had formally endorsed a single ESRD network, and existing affiliations among institutions supported a statewide network. ²

The Region III RHA's report on the meeting reflected the curious nature of medical politics at work in the situation: 3

The major issue of including three or more counties of Southern New Jersey in a Pennsylvania network was not clearly debated at the meeting. No proposal was made that it be included. Several representatives of New Jersey ESRD interests were present and they presented a unanimous point of view in favor of a New Jersey network. There was no opposition from Philadelphia representatives, including CHP, to the New Jersey plan.

Memorandum from Regional Health Administrator, Region III, to Michael J. Goran, M.D., Director, Bureau of Quality Assurance, "Development of Networks for the Delivery of End Stage Renal Disease (ESRD) Services," November 25, 1974.

Letter from John P. Capelli, M.D. to Mr. Thomas Budstibner, Regional Office, Department of Health, Education, and Welfare, October 14, 1974, "Re: ESRD Hospitals in Southern New Jersey for Network Participation."

³Op. cit., Memorandum, RHA, III, November 25, 1974.

Consequently, in recommending two ESRD networks within Region III, the RHA made no mention of New Jersey. Referring to Lourdes, however, he did discuss the "very complex situation involving a very large dialysis center in Camden which has developed plans to become a transplant center." He noted that the facility was part of a statewide plan, but that Camden was also part of the Philadelphia SMSA—which had six existing transplant centers, but complained that "accurate statistics for [patient referral patterns] seem impossible to obtain."

BQA then received a Region II proposal for a New Jersey network and silence from Region III. But BQA was deeply involved in network designation, and the Region III report on transplantation in the Philadelphia SMSA provided it ammunition to cleave New Jersey in two. It did so in the appendix to the NPRM of February 1975. The proposed Network No. 24 included all of Delaware, all of New Jersey except Bergen County, and 35 counties of Eastern Pennsylvania. Bergen County in northern New Jersey was included with metropolitan New York as the proposed Network No. 25.

BQA justified the division of New Jersey in this way:

It is logical that eastern Pennsylvania, southern New Jersey, and Delaware should be in the same network since within this medical service area, many institutions have long-standing affiliations with each other for the purposes of sharing resources to up-grade the quality of care, prevent the unnecessary acceleration of cost, and assure access to quality care for its patients. In addition, it is anticipated that with the implementation of P.L. 93-641 [the health planning act], the Philadelphia SMSA will remain intact and will become, or be part of, a health service area served by a Health Systems Agency (HSA) . . . It becomes imperative that this SMSA be a part of the same ESRD network.

The BQA arguments were developed more fully as New Jersey responded: many institutions in the area had long-standing resource-sharing affiliations; large networks were not necessarily ineffective;

¹Op. cit., Memorandum, Acting Administrator, HSA, February 24, 1975, Tab C, "Issues in Network Area Designations."

existing organizational arrangements were not identical in purpose with network objectives; and local consultants had not followed the suggested guidelines.

More significant, though the criterion of patient referral patterns was suggested as a guideline to the regions, no guidance was provided for the use of this concept, nor was a consistent methodology ever employed in applying it. BQA, in late March 1975, provided the HSA administrator with "raw data" on patient referral patterns for New Jersey and Philadelphia, gathered from Pennsylvania ESRD facilities. These data showed that "at least 82 New Jersey patients used Pennsylvania facilities during 1973." On the basis of the 1974 number of Medicare-eligible New Jersey residents, which was assumed to be larger than the 1973 number, it was calculated that "a minimum of 12 percent" of New Jersey patients were treated in Pennsylvania facilities. Seventeen known New Jersey patients received transplants in Pennsylvania in 1973, according to BQA, representing 14 percent of the transplants done in Philadelphia, or 22 percent of New Jersey patients receiving transplants in either Pennsylvania or New Jersey. The conclusion was "that a substantial number of New Jersey patients use Pennsylvania facilities for some level of their ESRD care," a fact made "all the more impressive" by the New Jersey effort to keep patients within its borders. These numbers would be challenged when they became available to New Jersey physicians--after the publication of the NPRM.

BQA also argued the need to preserve the Philadelphia SMSA within a single ESRD network, on the assumption that it would be designated as a single HSA. BQA wanted to establish networks in which patient population bore some relationship to existing transplantation centers,

Memorandum from Director, BQA, to Acting Administrator, Health Services Administration, "Data on Patient Referral Patterns in Illinois-Missouri and New Jersey-Pennsylvania," March 31, 1975.

The data neither represented a complete census of the patient population nor a random sample for either Pennsylvania or New Jersey, nor were the data for the numerator from the same period as those from the denominator, nor were they longitudinal.

to increase utilization of the existing centers, and to avoid certifying any new ones. Philadelphia, with six transplantation centers, had more than enough for the entire SMSA. BQA did not wish to approve Our Lady of Lourdes in Camden, which was seeking certification for transplantation purposes.

After publication of the NPRM on July 1, events occurred that led to the redesignation of New Jersey as a single network. First, on September 2, 1975, the regulations were published designating Health Service Areas (HSAs) for the entire country. The Philadelphia SMSA was not preserved! The seven southern counties of New Jersey were designated as a single HSA; four other HSAs were designated within New Jersey; and no designated HSA crossed New Jersey boundaries. BQA had wrongly anticipated the outcome of the health planning area designation process.

Second, negotiations between New Jersey physicians and HEW expanded to include others. Although public comment was submitted on the NPRM, all other channels of communication with HEW were also employed. The New Jersey Congressional delegation was mobilized to put pressure on HEW to modify the proposed regulations. Letters went primarily to James B. Cardwell, Commissioner of SSA, but also to Theodore Cooper, Assistant Secretary for Health.

On September 25, 1975, the New Jersey physicians and the New Jersey Congressional delegation met with HEW officials. 3 The case

⁴⁰ Federal Register 40306, September 2, 1975, "Designation of Health Service Areas."

²Representatives who wrote in behalf of a New Jersey network included Henry Helstoski, James J. Florio, Robert A. Roe, Edwin B. Forsythe, Matthew J. Rinaldo, Milicent Fenwick, Peter W. Rodino, Jr., Edward J. Patten, James J. Howard, and Andrew Maguire. Senator Clifford Case also wrote HEW.

³HEW was represented by Cooper, Tierney, van Hoek, Klar, and Jos. Background for the meeting was provided by Memorandum from Acting Administrator, HSA, to The Assistant Secretary for Health, "Briefing Material on ESRD Networks as They Relate to the State of New Jersey," September 18, 1975.

for a New Jersey network was presented, New Jersey physicians secured access to HEW data on patient referral patterns, and Capelli argued for certifying Lourdes as a transplant center. Cooper, retreating from the NPRM, indicated that initial information had led HEW to conclude that most South Jersey patients were being treated in Philadelphia. On the basis of the new information received that afternoon, however, reevaluation would be made and he asked for documentation of the patient referral patterns.

The following week, Representative James Florio transmitted the information to Cooper. The document criticized the HEW statistics for failing to reflect the "true shifts in total caseload of ESRD patients" in New Jersey and Pennsylvania. Although New Jersey's dialysis caseload had grown at a faster rate than Pennsylvania's from 1973 through 1974, the percent of New Jersey patients receiving care in Pennsylvania had declined, and a smaller portion of the new ESRD patients from New Jersey were being treated in Pennsylvania than the total proportion. HEW transplantation data, they also argued, did not accurately portray the shift from New Jersey reliance upon New York or Pennsylvania facilities. To the contrary, all data indicated a shift toward New Jersey patients being treated in New Jersey, thus undermining the BQA position that network designation was based upon patient referral patterns.

Finally, in late 1975, Our Lady of Lourdes was certified by HEW as a renal transplantation center, an event which Capelli had regarded as the key to a single New Jersey ESRD network. The New Jersey transplant facilities that had been "certified" through the grandfather provision of the interim regulations, though sufficient in number to meet the network requirement of the NPRM, were all located in north New Jersey and not easily accessible to South Jersey

Letter from James J. Florio, Member of Congress, to Dr. Theodore Cooper, Assistant Secretary of Health, September 29, 1975, conveying "Analysis of HEW Data on Determining ESRD Network for New Jersey."

²Events leading to HEW certification are summarized in "Our Lady of Lourdes Hospital Renal Transplant Program," prepared by Capelli, n.d.

residents. In fact, as Capelli knew, if South Jersey residents had to choose between North Jersey or Philadelphia transplant centers, it was more convenient and more familiar to cross the Delaware River to Philadelphia. Without a South Jersey transplant center, there was no way to discourage South Jersey patients from going to Pennsylvania for transplantation.

Before the enactment of P.L. 92-603, New Jersey had initiated an organ procurement effort and a cooperative organ-sharing arrangement with metropolitan New York. These statewide plans, however, did not include Lourdes as a transplant center. But, in May 1973, Lourdes applied to the New Jersey Health Facilities Planning Office for "certificate of need" approval for a transplant program. After review by the local CHP "B" agency, the New Jersey RMP, the New Jersey Chronic Renal Disease Advisory Committee, the State Health Planning Council, the New Jersey Commissioner of Health, and the Hospital Survey Committee of Philadelphia, the state granted Lourdes approval for a transplant program in December. State approval carried no weight with the HEW facility certification effort, but it allowed Lourdes to argue that a basis existed for its transplant program to have been certified at the time of the interim regulations. 1 Lourdes, in the belief that activity would be its own best justification, also initiated an active transplant program. From May 1974 through July 1975, 31 kidney transplants were performed there, 5 with living related donors and 26 with cadaveric donors. Twenty-eight kidneys were "harvested": 13 were used at Lourdes, 11 were sent to other institutions, and 4 were discarded as unusable. Of the total transplants performed, 19 had been done in the first six months of 1975; Lourdes projected that the hospital would perform 35 to 40 transplants in 1975, easily exceeding the minimum utilization rate set forth in the

The interim regulations provided that "consideration for participation will be given a facility that has, prior to June 1, 1973, made a substantial investment of time, study, and resources in preparation for provision of the services in question."

NPRM. Equally significant, Lourdes billed Medicare for reimbursement of these transplantation operations, and was reimbursed, even though the facility had no certified status as a transplant provider under the ESRD interim regulations!

In September 1975, when activity focused on the conflicting data about patient referral patterns, Capelli was able to claim that Lourdes was a functioning transplant center. It met a need for South New Jersey residents that was not adequately met by Philadelphia facilities, its transplant costs were substantially lower than those of the Philadelphia hospitals, and the underutilized Philadelphia facilities were simply seeking to insure their financial position at New Jersey's expense.

In late 1975, HEW faced a severe challenge to its division of New Jersey. The data supporting its claim of a "logical" patient referral pattern had been called into question, if not refuted. The Philadelphia SMSA had been divided in the political HSA designation process. The Lourdes transplant program represented a fait accompli. Under the circumstances, HEW modified its position. In November 1975, Lourdes was certified by HEW as an ESRD transplant facility. Soon thereafter, HEW decided to redesignate New Jersey as a single ESRD network, a decision formally announced in the final regulations of June 3, 1976.

ILLINOIS

The NPRM divided Illinois into three different networks: Proposed Network No. 9 consisted of Kansas and Missouri and the 68 counties of southern and central Illinois; Network No. 8 consisted of Iowa and Nebraska and three Illinois counties in the Davenport, Iowa SMSA; and Network No. 15 included 31 counties in northern Illinois. This proposed designation generated substantial controversy and a modification

Lourdes was a community hospital while the Philadelphia facilities were teaching hospitals of major university medical schools with substantially higher costs.

of the proposed networks. The changes were stated in the preamble to the final regulations:

The comments on proposed Network No. 9 were overwhelmingly in opposition to the "division of Illinois." Network No. 15 has been realigned to include the State of Illinois except for three counties in Network No. 8 and four counties which remain in Network No. 9. Exclusion of these counties from the Illinois Network No. 15 is based on facility affiliation arrangements and is congruent with the designated Health Service Areas surrounding the St. Louis and Davenport SMSA.

Conflict in Illinois arose from the process of area designation, the criteria determining preferences, and the application of these criteria. The conflict involved two SMSAs--Davenport, Iowa, and St. St. Louis, Missouri--but mainly the latter.

Region V, comprising Michigan, Ohio, Indiana, Illinois, Wisconsin, and Minnesota, recommended a single Illinois network, based on the consultants' recommendation. In early February 1975, the Regional Health Administrator responded to BQA questions by arguing for a single-state network: "We have serious concerns about not following the consultants' recommendations concerning an Illinois network." Region VII, consisting of Iowa, Missouri, Nebraska, and Kansas, meanwhile, had recommended two networks having long east-west axes. One included Nebraska, Iowa, and the Illinois counties in the Davenport SMSA. The other involved Kansas and Missouri--less 3 counties to Oklahoma and 4 to Tennessee, plus 34 counties of southern Illinois (identified as Illinois PSRO VIII).

¹41 Federal Register 22502, June 3, 1976.

²Memorandum from Regional Health Administrator, Region V, to Administrator, BQA, "Recommendations from Region V, ESRD Networks," February 4, 1975.

Memorandum from Regional Health Administrator, Region VII, to Robert van Hoek, M.D., Acting Administrator, Health Services Administration, "End Stage Renal Disease - Area Designation," September 2, 1975.

BQA accepted the first Region VII network and modified the second, rejecting the Region V recommendation in the process. The controversial Network No. 9 was to include Kansas and Missouri, plus 68 Illinois counties in the Illinois PSRO areas VI, VII, and VIII.

These conflicting recommendations and their resolution are shown in Table A-1, which indicates the number of Illinois counties recommended for each of the three proposed networks.

Table A-1

DISTRIBUTION OF ILLINOIS COUNTIES IN ESRD

NETWORK DESIGNATION PROPOSALS

Network	Region V Proposal	Region VII Proposal	NPRM Proposal	Final Rule
8	a	3	3	3
9	a	34	68	4
15	102	a	31	95

^aNo pertinent recommendation.

The criteria used by the Region V consultants were based upon two assumptions: 1

Networks were assumed to be administrative units which would not affect internetwork patient referral patterns. Regardless of where network lines are drawn, some patients always will be located at an interface with 2 or more networks. Any interference of network boundaries with patient referrals out-of-network would be unacceptable to physicians and patients alike.

Organization of networks along state lines was dictated primarily by the reality of reimbursement needs for costs not covered by Medicare. Several state renal programs

¹Letter from A. R. Lavender, M.D., chairman, ad hoc consultant group, Region V, to E. Frank Ellis, M.D., Regional Health Administrator, Region V, January 3, 1975.

reimburse facilities for costs of dialysis patients not yet eligible for Medicare, and also reimburse the 20% not covered by Medicare. Subdivision of these states would jeopardize continued support of state renal programs.

This second assumption stemmed from the fact that Illinois, since 1967, had been paying dialysis and transplant patient treatment charges for Illinois residents. Benefits were available to Illinois patients treated in state-certified facilities, both in Illinois and in nearby facilities in Indiana, Missouri, and Iowa. The Illinois program, widely regarded as a model program, not surprisingly had created a sense of identity among Illinois physicians, a program commitment by the Illinois Department of Public Health, and a strong belief that Illinois should be a single network.

The Region VII consultants and RHA, however, reasoned from a different perspective. Missouri's two largest cities—Kansas City and St. Louis—were at opposite ends of the state. Kansas City constituted a natural link between Missouri and Kansas, but it was necessary for Kansas City and St. Louis to be in the same network to meet the two transplant center criterion for network designation. But many patients treated in St. Louis came from southern Illinois and thus a "logical patient referral pattern" would include these counties in a Missouri network. So the recommended inclusion of 34 Illinois counties was based on the criterion of the non-division of PSRO boundaries. 1

BQA included the 34 southern Illinois counties into the Kansas-Missouri network on the basis of their relation to St. Louis ESRD facilities. But it also reasoned that relations between southern and central Illinois were strong enough to warrant including 34 counties from central Illinois PSRO areas VI and VII in the controversial

The attempted "raid" of the 34 Illinois counties in Region VII prompted the Region V RHA to amend his original recommendation to include the St. Louis SMSA counties from Illinois and Missouri in an Illinois network!

network. Data on patient referrals allegedly supported this conclusion.

The nature of the differences among the two RHAs and BQA threw into sharp relief the incompatibility among the criteria originally suggested by BQA for network designation. The issue of patient referral between networks, sharply posed by the Region V consultants, had not yet been resolved within HEW. One viewpoint at the time held that there should be no referral of patients across network boundaries, though this view did not prevail in the final regulations. Second, the relation of network boundaries to state reimbursement of charges not covered by Medicare was never a significant factor in BQA's thinking. Third, there was no logical basis for preferring PSRO boundaries to SMSA boundaries and no clear guidance from BQA on this issue. Fourth, the justification of networks on the basis of SMSA boundaries did not occur until the final regulations were decided upon. And finally, patient referral patterns were either inferred, but not measured, or based on clearly inadequate data.

The BQA recommendation was known well before publication of the NPRM, due to the widespread circulation of a draft NPRM. Thus, as early as March 1975, the Assistant Secretary for Health reported to the Secretary that the proposed designation was being "violently protested" by the Illinois State Department of Health. The proposed designations, he argued, were based "on both the need to preserve existing logical patient referral patterns and the need not to divide SMSAs to ensure compatibility with future Health Service Area designations." But the Illinois protest led HSA to re-examine its patient referral data and to meet with Illinois officials. On April 22, 1975, van Hoek, HSA, met with Dr. Joyce Lashoff, Director, Illinois Department of Public Health, but no change resulted in the HEW position.

The Illinois Public Health Department, aided by Illinois physicians, mobilized the Illinois Congressional delegation in a frontal

¹ Memorandum from Acting Assistant Secretary for Health to The Secretary, "End-Stage Renal Disease (ESRD) Network Proposals that Divide the State of Illinois - INFORMATION," March 20, 1975.

attack on the HEW position. A drumfire of criticism began in early 1975 and continued unabated for a full year. The basic arguments were that the proposed network designations would split up an existing, well-integrated system, and could lead the legislature—which had appropriated \$1 million per year since 1968, to reconsider its support for the program. HEW's standard defense was that southern and central Illinois, but not northern Illinois, should be included in the same network as St. Louis since they were related to each other through ESRD patient referral patterns.

In time, Illinois developed counterarguments that patient flow and referral patterns showed only a few counties of southern Illinois having significant ties to St. Louis. The secretary-treasurer of the Illinois Society of Nephrology, for example, wrote to Rep. Dan Rostenkowski that:

The rationale of the proposed federal boundaries is said to be to follow current patient flow and referral patterns. Sixty-six counties in central and southern Illinois are to be included in Network No. 9 with Missouri and Kansas, presumably because of patient referral to the St. Louis area. According to statistics of the Illinois Department of Health, fifty-four percent of ESRD patients in the four Illinois counties included in the St. Louis SMSA are related to Missouri facilities and the remainder are related to Illinois facilities. In the remaining sixty-two of the sixty-six Illinois counties only ten percent relate to Missouri facilities. There could possibly be some rationale in including the four counties of the St. Louis SMSA with Missouri and Kansas. However, it is obvious that the remaining sixty-two counties in the southern twothirds of Illinois have very minimal relationship to Missouri.

The following members of the House of Representatives were actively involved: Paul Simon, Melvin Price, Morgan F. Murphy, Henry J. Hyde, Carliss Collins, Paul Findley, Tim L. Hall, Philip M. Crane, Martin A. Russo, Robert M. Michel, and Tom Railsback. Both Senators—Adlai Stevenson and Charles Percy—were also active.

²Letter from E. T. Sorenson, M.D. to Representative Dan Rostenkowski, Member of Congress, September 9, 1975. Sorenson also pointed out that the Missouri facilities outside the St. Louis SMSA wanted only to be free to refer their patients to St. Louis, as necessary, and had no interest in relating to southern Illinois.

Illinois thus helped HEW to realize that it could maintain the St. Louis SMSA by the inclusion of only four southern Illinois counties in the Kansas-Missouri network.

Limiting the Kansas-Missouri "network" to the four Illinois counties in the St. Louis SMSA appealed to HEW on other grounds. The proposed network designations, HEW belatedly agreed, would disrupt evolving relations between medical education and medical practice in Illinois, which resulted from a statewide plan previously supported by a large, multi-year HEW grant. The plan divided the state into four northern regions and gave the University of Illinois responsibility for both expanding medical education and improving relations between medical education and medical practice. Separating the northern counties from central Illinois as the proposed ESRD networks would do, it was believed, would sever the University of Illinois School of Basic Medical Sciences in Urbana from its related College of Medicine in Chicago. Similarly, three southern regions of Illinois were to be under the aegis of Southern Illinois University School of Medicine. A single Illinois network would permit the continued development of closer patient referral patterns between southern and central Illinois as relations evolved between the Carbondale and Springfield campuses of Southern Illinois University. Whether HEW believed these arguments or merely used them as a convenient basis for changing its position is unclear.

In December, Goran reported on BQA's forced re-examination of the proposed Network No. 9. Illinois data showed that the proposed network, if unchanged, would disrupt "institutional networks" in the north; if changed to include only the four Illinois counties in the St. Louis SMSA, a comparable degree of disruption would result in the south. The latter was clearly preferable and the recommendation was

These relationships would later be called "institutional networks" as distinct from those of "geographic proximity."

²Memorandum from Director, BQA, to Associate Administrator for Operations, HSA, "Report on Analysis of ESRD Patient Data Submitted by the Illinois Department of Public Health (IDPH)," December 3, 1975.

to include these 4 counties in the Kansas-Missouri Network No. 9, but retain the other 64 counties in question in basically an Illinois Network No. 15. This solution would preserve the St. Louis SMSA and much of the St. Louis ESRD service area, without impairing the operations of the Illinois State Renal Program. Illinois had won a substantial victory.



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